PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 10. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 11. Add § 524.957 to read as follows:

§ 524.957 Florfenicol, terbinafine, and mometasone otic solution.

(a) *Specifications.* Each single-dose, prefilled dropperette contains 1 milliliter (mL) of a solution containing 15 milligrams (mg) florfenicol, 13.3 mg terbinafine, and 2 mg mometasone furoate.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer one dropperette (1 mL) per affected ear(s).

(2) *Indications for use.* For the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: (P≤21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

■ 13. In § 558.68, revise paragraph (c)(1) to read as follows:

§ 558.68 Avilamycin.

* * * * *

(c) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

* * * * *

■ 14. In § 558.261, revise paragraphs (c)(1) and (2) introductory text to read as follows:

§ 558.261 Florfenicol.

* * * * *

(c) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for florfenicol medicated feeds:

* * * * *

■ 15. In § 558.618, revise paragraph (c)(1) to read as follows:

§ 558.618 Tilmicosin.

* * * * *

(c) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

* * * * *

§ 558.625 [Amended]

■ 16. Effective December 21, 2015, in § 558.625, remove paragraph (b)(5) and redesignate paragraph (b)(6) as paragraph (b)(5).

§ 558.630 [Amended]

■ 17. Effective December 21, 2015, in § 558.630, in paragraph (b)(2), remove ''Nos. 054771 and 069254'' and in its place add ''No. 054771''.

Dated: December 4, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015–31042 Filed 12–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

[Docket No. FDA–2015–N–0002]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new animal drug applications (NADAs) and two abbreviated new animal drug applications (ANADAs). This action is being taken at the sponsors' requests because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective December 21, 2015.

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: The following three sponsors have requested that FDA withdraw approval of the NADAs and ANADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product name	21 CFR section
140–680 [1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405.	TYLAN (tylosin phosphate) Premix	558.625
140–681 [1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405.	TYLAN SULFA G (tylosin phosphate and sulfamethazine) Premix.	558.630
200–028	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.	EVICT 300 (pyrantel pamoate) Suspension	520.2043
200–383	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	CLINDAROBE (clindamycin) Capsules	520.446

[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 21 CFR 514.116 *Notice of withdrawal of approval of application,* notice is given that approval of NADA 140–680, NADA 140–681, ANADA 200–028, and ANADA 200–383, and all supplements and amendments thereto, is hereby withdrawn, effective December 21, 2015.

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: December 4, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015–31040 Filed 12–8–15; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0822; FRL–9939–52]

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of azoxystrobin in or on quinoa grain, ti leaves, ti roots, and modifies the existing tolerances for the stone fruit group 12 and tree nut group 14 to read ''stone fruit group 12–12'' and ''tree nut group 14–12, except pistachio'' respectively. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 9, 2015. Objections and requests for hearings must be received on or before February 8, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0822, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2014–0822 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 8, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2014–0822, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 4, 2015 (80 FR 11611) (FRL–9922–68), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8319) by IR–4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of azoxystrobin (methyl (E)-2-{2-[6-(2-cyanophenoxy) pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) and the Z isomer of azoxystrobin (methyl (Z)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) in or on the raw agricultural commodities ti palm, leaves at 50 parts per million (ppm); ti palm, roots at 0.5 ppm; fruit, stone, group 12–12 at 2.0 ppm; and nut, tree, group 14–12 at 0.02 ppm. Upon the approval of the aforementioned tolerances, the petitioner requested to remove the established tolerances for azoxystrobin in or on the raw agricultural commodities fruit, stone, group 12 at 1.5 ppm; and nut, tree, group 14 at 0.02 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.* EPA received two comments in response to the March 4, 2015 Notice of Filing that simply said ''Good.''

In the **Federal Register** of October 21, 2015 (80 FR 63731) (FRL–9935–29), EPA amended the initial notice of filing for pesticide petition (PP 4E8319), including the commodity quinoa grain at 3.0 ppm in addition to the commodities originally requested and listed above. Comments were received