

List of Commenters⁵²

American Gas Association (AGA) filed comments in Docket Nos. RM96-1-030 and RM96-1-036 and reply comments in Docket No. RM96-1-030.

Arizona Public Service Company (APS) filed comments in Docket No. RM96-1-030.

Carolina Gas Transmission Company (Carolina) filed comments in Docket Nos. RM96-1-030 and RM96-1-036.

El Paso Corporation (El Paso) filed comments in Docket No. RM96-1-036.

Interstate Natural Gas Association of America (INGAA) filed comments and an answer in Docket No. RM96-1-030.

Natural Gas Supply Association (NGSA) filed comments in Docket No. RM96-1-030 (late filed).

New Jersey Natural Gas Company & PSEG Energy Resources & Trade LLC (NJN/PSEG) filed comments in Docket No. RM96-1-030.

Tennessee Valley Authority (TVA) filed comments in Docket No. RM96-1-030.

Appendix B

Note: The following Appendix will not appear in the Code of Federal Regulations.

Recommended Tariff Provision*General Terms and Conditions*

Compliance with 18 CFR, Section 284.12

Transporter has adopted all of the Business Practices and Electronic Communications Standards which are required by the Commission in 18 CFR, Section 284.12(a), as amended from time to time, in accordance with Order No. 587, *et al.* In addition to the NAESB WGQ Standards referenced elsewhere in the Tariff, Transporter specifically incorporates by reference the following NAESB WGQ Version 1.9 Standards, Definitions, and Data Sets, by reference:

Additional Standards:

General:

Principles (Optional): 0.1.1, 0.1.2, 0.1.3
Standards: 0.3.1, 0.3.2, 0.3.16, 0.3.17

Creditworthiness:

Standards: 0.3.3, 0.3.4, 0.3.5, 0.3.6, 0.3.7, 0.3.8, 0.3.9, 0.3.10

Gas/Electric Operational Communications:

Definitions: 0.2.1, 0.2.2, 0.2.3
Standards: 0.3.11, 0.3.12, 0.3.13, 0.3.14, 0.3.15

Storage Information:

Data Sets: 0.4.1

Nominations Related Standards:

Principles (Optional): 1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.7, 1.1.9, 1.1.10, 1.1.11, 1.1.12, 1.1.13, 1.1.14, 1.1.15, 1.1.16, 1.1.17, 1.1.18, 1.1.20, 1.1.21, 1.1.22
Definitions: 1.2.1, 1.2.2, 1.2.3, 1.2.4, 1.2.5, 1.2.6, 1.2.8, 1.2.9, 1.2.10, 1.2.11, 1.2.12, 1.2.13, 1.2.14, 1.2.15, 1.2.16, 1.2.17, 1.2.18, 1.2.19
Standards: 1.3.1, 1.3.2(vi), 1.3.3, 1.3.4, 1.3.5, 1.3.6, 1.3.7, 1.3.8, 1.3.9, 1.3.11, 1.3.13, 1.3.14, 1.3.15, 1.3.16, 1.3.17,

1.3.18, 1.3.19, 1.3.20, 1.3.21, 1.3.22, 1.3.23, 1.3.24, 1.3.25, 1.3.26, 1.3.27, 1.3.28, 1.3.29, 1.3.30, 1.3.31, 1.3.32, 1.3.33, 1.3.34, 1.3.35, 1.3.36, 1.3.37, 1.3.38, 1.3.39, 1.3.40, 1.3.41, 1.3.42, 1.3.43, 1.3.44, 1.3.45, 1.3.46, 1.3.47, 1.3.48, 1.3.49, 1.3.50, 1.3.51, 1.3.52, 1.3.53, 1.3.54, 1.3.55, 1.3.56, 1.3.57, 1.3.58, 1.3.59, 1.3.60, 1.3.61, 1.3.62, 1.3.63, 1.3.64, 1.3.65, 1.3.66, 1.3.67, 1.3.68, 1.3.69, 1.3.70, 1.3.71, 1.3.72, 1.3.73, 1.3.74, 1.3.75, 1.3.76, 1.3.77, 1.3.79, 1.3.80

Data Sets: 1.4.1, 1.4.2, 1.4.3, 1.4.4, 1.4.5, 1.4.6, 1.4.7

Flowing Gas Related Standards:

Principles (Optional): 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6

Definitions: 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5
Standards: 2.3.1, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.3.6, 2.3.7, 2.3.8, 2.3.9, 2.3.10, 2.3.11, 2.3.12, 2.3.13, 2.3.14, 2.3.15, 2.3.16, 2.3.17, 2.3.18, 2.3.19, 2.3.20, 2.3.21, 2.3.22, 2.3.23, 2.3.25, 2.3.26, 2.3.27, 2.3.28, 2.3.29, 2.3.30, 2.3.31, 2.3.32, 2.3.33, 2.3.34, 2.3.35, 2.3.40, 2.3.41, 2.3.42, 2.3.43, 2.3.44, 2.3.45, 2.3.46, 2.3.47, 2.3.48, 2.3.49, 2.3.50, 2.3.51, 2.3.52, 2.3.53, 2.3.54, 2.3.55, 2.3.56, 2.3.57, 2.3.58, 2.3.59, 2.3.60, 2.3.61, 2.3.62, 2.3.63, 2.3.64, 2.3.65

Data Sets: 2.4.1, 2.4.2, 2.4.3, 2.4.4, 2.4.5, 2.4.6, 2.4.7, 2.4.8, 2.4.9, 2.4.10, 2.4.11, 2.4.12, 2.4.13, 2.4.14, 2.4.15, 2.4.16, 2.4.17, 2.4.18

Invoicing Related Standards:

Principles (Optional): 3.1.1, 3.1.2

Definition: 3.2.1

Standards: 3.3.1, 3.3.2, 3.3.3, 3.3.4, 3.3.5, 3.3.6, 3.3.7, 3.3.8, 3.3.9, 3.3.10, 3.3.11, 3.3.12, 3.3.13, 3.3.14, 3.3.15, 3.3.16, 3.3.17, 3.3.18, 3.3.19, 3.3.20, 3.3.21, 3.3.22, 3.3.23, 3.3.24, 3.3.25, 3.3.26

Data Sets: 3.4.1, 3.4.2, 3.4.3, 3.4.4

Quadrant Electronic Delivery Mechanism Related Standards:

Principles (Optional): 4.1.2, 4.1.3, 4.1.4, 4.1.6, 4.1.7, 4.1.10, 4.1.12, 4.1.13, 4.1.15, 4.1.16, 4.1.17, 4.1.18, 4.1.19, 4.1.20, 4.1.21, 4.1.22, 4.1.23, 4.1.24, 4.1.26, 4.1.27, 4.1.28, 4.1.29, 4.1.30, 4.1.31, 4.1.32, 4.1.33, 4.1.34, 4.1.35, 4.1.36, 4.1.37, 4.1.38, 4.1.39, 4.1.40

Definitions: 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.2.7, 4.2.8, 4.2.9, 4.2.10, 4.2.11, 4.2.12, 4.2.13, 4.2.14, 4.2.15, 4.2.16, 4.2.17, 4.2.18, 4.2.19, 4.2.20

Standards: 4.3.1, 4.3.2, 4.3.3, 4.3.5, 4.3.16, 4.3.17, 4.3.18, 4.3.20, 4.3.22, 4.3.23, 4.3.24, 4.3.25, 4.3.26, 4.3.27, 4.3.28, 4.3.29, 4.3.30, 4.3.31, 4.3.32, 4.3.33, 4.3.34, 4.3.35, 4.3.36, 4.3.38, 4.3.39, 4.3.40, 4.3.41, 4.3.42, 4.3.43, 4.3.44, 4.3.45, 4.3.46, 4.3.47, 4.3.48, 4.3.49, 4.3.50, 4.3.51, 4.3.52, 4.3.53, 4.3.54, 4.3.55, 4.3.56, 4.3.57, 4.3.58, 4.3.59, 4.3.60, 4.3.61, 4.3.62, 4.3.65, 4.3.66, 4.3.67, 4.3.68, 4.3.69, 4.3.72, 4.3.73, 4.3.74, 4.3.75, 4.3.76, 4.3.78, 4.3.79, 4.3.80, 4.3.81, 4.3.82, 4.3.83, 4.3.84, 4.3.85, 4.3.86, 4.3.87, 4.3.89, 4.3.90, 4.3.91, 4.3.92, 4.3.93, 4.3.94, 4.3.95, 4.3.96, 4.3.97, 4.3.98, 4.3.99

Capacity Release Standards:

Principles (Optional): 5.1.1, 5.1.2, 5.1.3, 5.1.4

Definitions: 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5
Standards: 5.3.1, 5.3.3, 5.3.4, 5.3.5, 5.3.7, 5.3.8, 5.3.9, 5.3.10, 5.3.11, 5.3.12, 5.3.13, 5.3.14, 5.3.15, 5.3.16, 5.3.17, 5.3.18, 5.3.19, 5.3.20, 5.3.21, 5.3.22, 5.3.23, 5.3.24, 5.3.25, 5.3.26, 5.3.27, 5.3.28, 5.3.29, 5.3.30, 5.3.31, 5.3.32, 5.3.33, 5.3.34, 5.3.35, 5.3.36, 5.3.37, 5.3.38, 5.3.39, 5.3.40, 5.3.41, 5.3.42, 5.3.43, 5.3.44, 5.3.45, 5.3.46, 5.3.47, 5.3.48, 5.3.49, 5.3.50, 5.3.51, 5.3.52, 5.3.53, 5.3.54, 5.3.55, 5.3.56, 5.3.57, 5.3.58, 5.3.59, 5.3.60, 5.3.61, 5.3.62, 5.3.62a, 5.3.63, 5.3.64, 5.3.65, 5.3.66, 5.3.67, 5.3.68, 5.3.69

Data Sets: 5.4.1, 5.4.2, 5.4.3, 5.4.4, 5.4.5, 5.4.6, 5.4.7, 5.4.8, 5.4.9, 5.4.10, 5.4.11, 5.4.12, 5.4.13, 5.4.14, 5.4.15, 5.4.16, 5.4.17, 5.4.18, 5.4.19, 5.4.20, 5.4.21, 5.4.22, 5.4.23

Internet Electronic Transport Related Standards:

Principles (Optional): 10.1.1, 10.1.2, 10.2.3, 10.2.4, 10.2.5, 10.2.6, 10.2.7, 10.2.8, 10.1.9, 10.1.10

Definitions: 10.2.1, 10.2.2, 10.2.3, 10.2.4, 10.2.5, 10.2.6, 10.2.7, 10.2.8, 10.2.9, 10.2.10, 10.2.11, 10.2.12, 10.2.13, 10.2.14, 10.2.15, 10.2.16, 10.2.17, 10.2.18, 10.2.19, 10.2.20, 10.2.21, 10.2.22, 10.2.23, 10.2.24, 10.2.25, 10.2.26, 10.2.27, 10.2.28, 10.2.29, 10.2.30, 10.2.31, 10.2.32, 10.2.33, 10.2.34, 10.2.35, 10.2.36, 10.2.37, 10.2.38
Standards: 10.3.1, 10.3.3, 10.3.4, 10.3.5, 10.3.6, 10.3.7, 10.3.8, 10.3.9, 10.3.10, 10.3.11, 10.3.12, 10.3.14, 10.3.15, 10.3.16, 10.3.17, 10.3.18, 10.3.19, 10.3.20, 10.3.21, 10.3.22, 10.3.23, 10.3.24, 10.3.25, 10.3.26, 10.3.27

[FR Doc. 2010-6976 Filed 3-31-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 10**

[Docket No. FDA-1999-N-3539] (formerly Docket No. 1999N-4783)

Administrative Practices and Procedures; Good Guidance Practices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its administrative regulations. This action is being taken to ensure accuracy and clarity in agency regulations.

DATES: The rule is effective April 1, 2010.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy (HF-27), Food and Drug Administration, 5600

⁵² The abbreviations used to refer to these commenters in this Final Rule are shown parenthetically.

Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: FDA is amending its administrative regulations in 21 CFR part 10. We are taking this action to ensure accuracy and clarity in the agency's regulations.

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because the amendments to the regulations provide only technical changes to correct inaccurate citations and to update terminology, and are nonsubstantive.

List of Subjects in 21 CFR Part 10

Administrative practice and procedure, News media.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 10 is amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

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

Authority: 5 U.S.C. 551-558, 701-706; 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-397, 467E, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

■ 2. In § 10.90, revise paragraphs (a) and (c) to read as follows:

§ 10.90 Food and Drug Administration regulations, recommendations, and agreements.

(a) *Regulations.* FDA regulations are issued in the **Federal Register** under § 10.40 or § 10.50 and codified in the Code of Federal Regulations. Regulations may contain provisions that will be enforced as legal requirements, or which are intended only as guidance documents and recommendations, or both. The dissemination of draft notices and regulations is subject to § 10.80.

(c) *Recommendations.* In addition to the guidance documents subject to § 10.115, FDA often formulates and disseminates recommendations about matters which are authorized by, but do not involve direct regulatory action under, the laws administered by the Commissioner, e.g., model State and local ordinances, or personnel practices for reducing radiation exposure, issued under 42 U.S.C. 243 and 21 U.S.C. 360ii. These recommendations may, in the discretion of the Commissioner, be handled under the procedures established in § 10.115, except that the recommendations will be included in a

separate public file of recommendations established by the Division of Dockets Management and will be separated from the guidance documents in the notice of availability published in the **Federal Register**, or be published in the **Federal Register** as regulations under paragraph (a) of this section.

* * * * *

Dated: March 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-7286 Filed 3-31-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

[Docket No. FDA-2010-N-0002]

Ophthalmic and Topical Dosage Form New Animal Drugs; Orbifloxacin, Mometasone Furoate Monohydrate, and Posaconazole Suspension

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 new animal drug application (NADA) filed by Intervet, Inc. The NADA provides for the veterinary prescription use of a suspension containing orbifloxacin, mometasone furoate monohydrate, and posaconazole for the treatment of otitis externa in dogs.

DATES: This rule is effective April 1, 2010.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, email: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068, filed NADA 141-266 that provides for veterinary prescription use of POSATEX (orbifloxacin, mometasone furoate monohydrate, and posaconazole) Otic Suspension for the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (coagulase-positive staphylococci, *Pseudomonas aeruginosa*, and *Enterococcus faecalis*). The NADA is approved as of February 18, 2010, and the regulations are amended in 21 CFR part 524 by adding § 524.1610 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date 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 in 21 CFR Part 524

Animal drugs.

■ 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 part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 2. Add § 524.1610 to read as follows:

§ 524.1610 Orbifloxacin, mometasone furoate monohydrate, and posaconazole suspension.

(a) *Specifications.* Each gram of suspension contains 10 milligrams (mg) orbifloxacin, mometasone furoate monohydrate equivalent to 1 mg mometasone furoate, and 1 mg posaconazole.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* For dogs weighing less than 30 lbs. instill 4 drops once daily into the ear canal. For dogs weighing 30 lbs. or more, instill 8 drops into the ear canal. Therapy should continue for 7 consecutive days.