Drug labeler code	Firm name and address
* * * * *	
051072	Aurora Pharmaceutical, LLC, 1196 Highway 3 South, Northfield, MN 55057–3009
* * * * *	
086001	SmartVet USA, Inc., 22201 West Innovation Dr., Suite 170A, Olathe, KS 66061–1304
* * * * *	

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.

■ 4. Revise § 520.2612 to read as follows:

§ 520.2612 Trimethoprim and sulfadiazine suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains:

(1) 10 milligrams (mg) trimethoprim and 50 mg sulfadiazine; or

(2) 400 mg combined active ingredients (67 mg trimethoprim and 333 mg sulfadiazine).

(b) *Sponsors.* See sponsor numbers in § 510.600 of this chapter:

(1) No. 000061 for use of product described in paragraph (a)(1) for use as in paragraph (c)(1) of this section.

(2) No. 051072 for use of product described in paragraph (a)(2) for use as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 1 mL (10 mg trimethoprim and 50 mg sulfadiazine) per 5 pounds (lb) of body weight once daily, or one-half the recommended daily dose every 12 hours, for up to 14 consecutive days.

(ii) *Indications for use.* The drug is used in dogs where systemic antibacterial action against sensitive organisms is required, either alone or as an adjunct to surgery or debridement with associated infection. The drug is indicated where control of bacterial infection is required during the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, wound infections, and abscesses.

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

(2) *Horses*—(i) *Amount.* Administer 24 mg combined active ingredients per kilogram of body weight (2.7 mL/100 lb) twice daily for 10 days.

(ii) *Indications for use.* For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* subsp. *zooepidemicus.*

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 5. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 6. Revise § 522.1077 to read as follows:

§ 522.1077 Gonadorelin hydrochloride.

(a) *Specifications.* Each milliliter of solution contains 50 micrograms (mcg) of gonadorelin (as hydrochloride).

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle*—(1) *Indications for use and amounts*—(i) For the treatment of ovarian follicular cysts in cattle, administer 100 mcg gonadorelin by intramuscular injection.

(ii) For use with dinoprost tromethamine to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows, administer to each cow 100 to 200 mcg gonadorelin by intramuscular injection, followed 6 to 8 days later by 25 mg dinoprost tromethamine by intramuscular injection, followed 30 to 72 hours later by 100 to 200 mcg gonadorelin by intramuscular injection.

(2) *Limitations.* Dinoprost tromethamine as provided by sponsor No. 054771 in § 510.600(c) of this chapter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 7. In § 522.2630, revise paragraphs (a) and (b) to read as follows:

§ 522.2630 Tulathromycin.

(a) *Specifications.* Each milliliter of solution contains:

(1) 100 milligrams (mg) tulathromycin

(2) 25 mg tulathromycin

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) Product described as in paragraph (a)(1) for use as in paragraph (d).

(2) Product described as in paragraph (a)(2) for use as in paragraph (d)(2).

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1193 [Amended]

■ 9. In paragraph (b)(2) of § 524.1193, remove ''066916'' and in its place add ''086001''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.500 [Amended]

■ 11. In § 558.500, in paragraph (a), remove ''45'' and in its place add ''45.4''; in paragraph (b), remove ''No. 000986'' and in its place add ''Nos. 000986 and 054771''; in the table in paragraph (e)(1), in the ''Ractopamine in grams/ton'' column, remove ''4.5 to 9'' wherever it occurs and in its place add ''4.5 to 9.0''; and in the table in paragraphs (e)(1)(i), (e)(2)(i), (e)(2)(vi), and (e)(2)(xi), in the ''Sponsor'' column, add ''054771''.

Dated: October 22, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013–25172 Filed 10–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1240

[Docket No. FDA–2013–N–0639]

Turtles Intrastate and Interstate Requirements

Correction

In rule document 2013–17751 appearing on pages 44878–44881 in the issue of July 25, 2013, make the following correction:

On page 44879, in the first column, under the **DATES** heading, in the first and second lines, ''January 16, 2014'' should read ''December 9, 2013''.

[FR Doc. C1–2013–17751 Filed 10–24–13; 8:45 am]

BILLING CODE 1505–01–D