

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 510 and 522

#### New Animal Drugs; Change of Sponsor; Fomepizole

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

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) for fomepizole solution for injection from Orphan Medical, Inc., to Jazz Pharmaceuticals, Inc. The regulations are also being amended to reflect approval of a supplemental NADA to remove a vial of saline diluent from this product.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Orphan Medical, Inc., 13911 Ridgedale Dr., suite 475, Minnetonka, MN 55305, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141-075 for ANTIZOL-VET (fomepizole) to Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304. A supplement was also filed to NADA 141-075 to remove a vial of saline diluent from this product. The supplemental NADA is approved as of April 18, 2006, and the regulations are amended in 21 CFR 522.1004 to reflect

the change of sponsorship, the removal of a vial of saline diluent from the product, and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

Following these changes of sponsorship, Orphan Medical, Inc., is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for Orphan Medical, Inc.

The agency has determined under 21 CFR 25.33(d)(1) 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.

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 522*

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 parts 510 and 522 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.

- 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for “Orphan Medical, Inc.” and alphabetically add a new entry for “Jazz Pharmaceuticals, Inc.”; and in the table in paragraph (c)(2) remove the entry for “062161” and numerically add a new entry for “068727” to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

Firm name and address	Drug labeler code
Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304.	068727

(2) \* \* \*

Drug labeler code	Firm name and address
068727	Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

- 3. The authority citation for 21 CFR part 522 continues to read as follows:

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

- 4. In § 522.1004, revise paragraphs (a), (b), (c)(1), and (c)(3) to read as follows:

**§ 522.1004 Fomepizole.**

(a) *Specifications.* Each vial contains 1.5 grams fomepizole (1.5 milliliter (mL) of 1.0 gram per mL solution).

(b) *Sponsor.* See No. 068727 in § 510.600(c) of this chapter.

(c) \* \* \*

(1) *Amount.* 20 milligrams per kilogram (mg/kg) of body weight intravenously initially, followed by 15 mg/kg at 12 and 24 hours, and 5 mg/kg at 36 hours.

\* \* \* \* \*

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

Dated: May 3, 2006.

**Steven D. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

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