

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(9) 6.8 to 24 .....	Monensin 10 to 40, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium (Actinomyces) pyogenes</i> ; and for suppression of estrus (heat).	Feed continuously to heifers during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. See §§ 558.342(d), 558.355(d), and 558.625(c). Monensin and tylosin as provided by No. 000986; melengestrol acetate as provided by No. 054771 in § 510.600(c) of this chapter. Withdrawal period: 3 days.	000061

Dated: April 3, 2015.

**Bernadette Dunham,**  
Director, Center for Veterinary Medicine.  
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BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

[Docket No. FDA-2015-N-0002]

#### Implantation or Injectable Dosage Form New Animal Drugs; Withdrawal of Approval of New Animal Drug Application; Fomepizole

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

**ACTION:** Notification of withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) for a fomepizole injectable solution used as an antidote for ethylene glycol poisoning in dogs. This action is being taken at the sponsor's request because this product is no longer manufactured or marketed.

**DATES:** Withdrawal of approval is effective April 20, 2015.

**FOR FURTHER INFORMATION CONTACT:** Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9075, [sujaya.dessai@fda.hhs.gov](mailto:sujaya.dessai@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Paladin Labs (USA), Inc., 160 Greentree Dr., suite 101, Dover, DE 19904 has requested that FDA withdraw approval of NADA 141-075 for ANTIZOL-VET (fomepizole) Injection because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 141-075, and all supplements and amendments thereto, is hereby withdrawn.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of this application.

Dated: April 3, 2015.

**Bernadette Dunham,**  
Director, Center for Veterinary Medicine.  
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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 260 and 261

[EPA-HQ-RCRA-2015-0118; FRL\_9923-12-OSWER]

#### Response to Vacaturs of the Comparable Fuels Rule and the Gasification Rule

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is revising regulations associated with the comparable fuels exclusion and the gasification exclusion, originally issued by EPA under the Resource Conservation and Recovery Act (RCRA). These revisions implement vacaturs ordered by the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit), on June 27, 2014.

**DATES:** Effective April 8, 2015.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA-HQ-RCRA-2015-0118. All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through [www.regulations.gov](http://www.regulations.gov) or in hard copy at the EPA Docket Center, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. 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 RCRA Docket is (202) 566-0270.

**FOR FURTHER INFORMATION CONTACT:** Office of Resource Conservation and Recovery, Materials Recovery and Waste Management Division, MC 5304P, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460, Tracy Atagi, at (703) 308-8672, ([atagi.tracy@epa.gov](mailto:atagi.tracy@epa.gov)) or Frank Behan, at (703) 308-8476, [behan.frank@epa.gov](mailto:behan.frank@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Preamble Outline

- I. General Information
- II. Statutory Authority
- III. Which regulations is EPA removing?
- IV. Background on the Comparable Fuels Rule and the Gasification Rule
- V. When will the final rule become effective?
- VI. State Authorization
- VII. Statutory and Executive Order (EO) Reviews