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 [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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.

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(21 CFR 514.116), notice is given that approval of NADA 141-075, and all supplements and amendments thereto, is hereby withdrawn.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.

[FR Doc. 2015-08024 Filed: 4/7/2015 08:45 am; Publication Date: 4/8/2015]