



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 529

[Docket No. FDA-2019-N-0002]

New Animal Drugs; Withdrawal of Approval of a New Animal Drug Application; Withdrawal of Approval of Abbreviated New Animal Drug Applications

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) and two abbreviated new animal drug applications (ANADAs) at the sponsors' request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is applicable [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, 240-402-5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234, has requested that FDA withdraw approval of NADA 010-005 for use of WAZINE (dipiperazine sulfate and piperazine hydrochloride) Soluble Powders because the product is no longer manufactured or marketed.

Also, Halocarbon Products Corp., 6525 The Corners Pkwy., suite 200, Peachtree Corners, GA 30092, has requested that FDA withdraw approval of ANADA 200-200 for use of Halothane USP (halothane) because the product is no longer manufactured or marketed.

Lastly, Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103, has requested that FDA withdraw approval of ANADA 200-472 for use of Fomepizole Injection because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 010-005 and ANADAs 200-200 and 200-472, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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

Dated: January 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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