4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 522

[Docket No. FDA-2019-N-5405]

New Animal Drugs; Withdrawal of Approval of 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 seven new animal drug applications (NADAs) from multiple holders of these applications. The basis for the withdrawals is that the holders of these applications have repeatedly failed to file required annual reports for the applications.

DATES: Withdrawal of approval is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5720, david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new animal drugs are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 514.80 (21 CFR 514.80).

In the *Federal Register* of January 8, 2020 (85 FR 919), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of seven NADAs because the sponsors had failed to submit the required annual reports for these applications. The holders of these applications did not respond to the NOOH. Failure to file a written notice of participation and request for a hearing as required by § 514.200(b) (21 CFR 514.200(b)) constitutes an election by the applicant not to make use of the opportunity for a hearing

concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, approval of the seven applications listed in table 1 is being withdrawn.

Table 1.--NADAs for Which Approval Is Withdrawn

Application No.	Trade Name (drug)	Sponsor
031-971	CUPRATE (cupric glycinate)	Walco International, Inc., 15 West Putnam, Porterville, CA 93257
045-863	PALOSEIN (orgotein)	OXIS International, Inc., 6040 N. Cutter Circle, suite 317, Portland, OR 97217-3935
046-922	SERGEANTS SURE SHOT (*n*-butyl chloride) Capsules	ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105
046-923	SERGEANTS (*n*-butyl chloride) Puppy Worm Capsules	ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105
065-067	Tetracycline Hydrochloride Tablets	Premo Pharmaceutical Laboratories, Inc., 111 Leuning St., South Hackensack, NJ 07606
140-850	ELITE (dichlorophene and toluene) Dog and Cat Wormer	RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620
141-107	BAPTEN for Injection (ß-aminopropionitrile fumarate)	Alaco, Inc., 1500 North Wilmot Rd., suite 290-C, Tucson, AZ 85712

The Commissioner of Food and Drugs (the Commissioner), under section 512(e)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e)(2)(A)), finds that the holders of the applications listed in this document have repeatedly failed to submit reports required by § 514.80. In addition, under § 514.200(b), the Commissioner finds that the holders of the applications have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the applications listed in this document, and all amendments and supplements thereto, is hereby withdrawn, effective [INSERT 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 withdrawal of approval of these applications.

Dated: February 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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