appropriate guidance to CBP personnel on the continued implementation of the temporary measures set forth in this Notification. The CBP Commissioner may determine that other forms of travel, such as travel in furtherance of economic stability or social order, constitute ''essential travel'' under this Notification. Further, the CBP Commissioner may, on an individualized basis and for humanitarian reasons or for other purposes in the national interest, permit the processing of travelers to the United States not engaged in ''essential travel.''

Alejandro N. Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2021–03776 Filed 2–19–21; 11:15 am]

BILLING CODE 9111–FP–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 Drug Applications; Beta-Aminopropionitrile Fumarate; *n*-Butyl Chloride; Cupric Glycinate Injection; Dichlorophene and Toluene; Orgotein for Injection; Tetracycline Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of seven new animal drug applications (NADAs) for lack of compliance with the reporting requirements in an FDA regulation.

DATES: This rule is effective February 23, 2021.

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:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of the seven NADAs listed in table 1, and all supplements and amendments thereto, is withdrawn, effective February 23, 2021, for lack of compliance with reporting requirements in 21 CFR 514.80. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect withdrawal of approval of the following applications and a current format. Withdrawal of approval of NADA 065–067 for Tetracycline Hydrochloride (HCl) Tablets did not require amending the regulations.

TABLE 1—NADAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Trade name (drug)	Sponsor	21 CFR section
031–971	CUPRATE (cupric glycinate)	Walco International, Inc., 15 West Putnam, Porterville, CA 93257.	522.518
045–863	PALOSEIN (orgotein)	OXIS International, Inc., 6040 N Cutter Circle, Suite 317, Portland, OR 97217–3935.	522.1620
046–922	SERGEANTS SURE SHOT (*n*-butyl chloride) Capsules.	ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105.	520.260
046–923	SERGEANTS (*n*-butyl chloride) Puppy Worm Capsules.	ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105.	520.260
065–067	Tetracycline HCl Tablets	Premo Pharmaceutical Laboratories, Inc., 111 Leuning St., South Hackensack, NJ 07606.	Not codified
140–850	ELITE (dichlorophene and toluene) Dog and Cat Wormer.	RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620.	520.580
141–107	BAPTEN for Injection (ß-aminopropionitrile fumarate).	Alaco, Inc., 1500 North Wilmot Rd., Suite 290–C, Tucson, AZ 85712.	522.84

Following these withdrawals of approval, Alaco, Inc.; ConAgra Pet Products Co.; OXIS International, Inc.; RSR Laboratories, Inc.; and Walco International, Inc., are no longer the sponsors of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

II. Legal Authority

This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities. This rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires **Federal Register** publication of the conditions of use of an approved or conditionally approved new animal drug and the name and address of the drug's sponsor in a ''notice, which upon publication shall be effective as a regulation.'' A notice published pursuant to section 512(i) is not subject to the notice-and-comment rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. 551 *et seq.* See section 512(i) of the FD&C Act (21 U.S.C. 360b(i)); 21 CFR 10.40(e)(3); S. Rep. 90–1308, at 5 (1968).

This document 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. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as ''an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.''

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 520, and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entries for ''Alaco, Inc.'', ''OXIS International, Inc.'', ''RSR Laboratories, Inc.'', and ''Walco International, Inc.''; and in the table in paragraph (c)(2), remove the entries for ''024991'', ''049185'', ''058670'', and ''064146''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for part 520 continues to read as follows:

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

■ 4. Revise § 520.260 to read as follows:

§ 520.260 *n*-Butyl chloride.

(a) *Specifications.* Each capsule contains 221, 442, 884, or 1,768 milligrams (mg); or 4.42 grams of *n*-butyl chloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) No. 023851 for capsules containing 221, 442, 884, or 1,768 mg, or 4.42 grams (g); and

(2) No. 054771 for capsules containing 221 mg.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer capsules orally based on body weight as follows:

(i) Capsules containing 221 mg: Under 5 pounds, 1 capsule per 1¼ pounds of body weight.

(ii) Capsules containing 442 mg: Under 5 pounds, 1 capsule per 2½ pounds of body weight.

(iii) Capsules containing 884 mg:

(A) Under 5 pounds, 1 capsule;

(B) 5 to 10 pounds, 2 capsules;

(C) 10 to 20 pounds, 3 capsules;

(D) 20 to 40 pounds, 4 capsules;

(E) Over 40 pounds, 5 capsules.

(iv) Capsules containing 1,768 mg: Dogs weighing 5 to 10 pounds, 1 capsule.

(v) Capsules containing 4.42 g: Dogs weighing 40 pounds or over, 1 capsule.

(2) *Indications for use.* For the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum, Ancylostoma braziliense,* and *Uncinaria stenocephala*) from dogs.

(3) *Limitations.* Dogs should not be fed for 18 to 24 hours before being given the drug. Administration of the drug should be followed in ½ to 1 hour with a mild cathartic. Normal feeding may be resumed 4 to 8 hours after treatment. Animals subject to reinfection may be retreated in 2 weeks. A veterinarian should be consulted before using in severely debilitated dogs.

§ 520.580 [Amended]

■ 5. In § 520.580, in paragraph (b)(1), remove ''Nos. 017135, 023851, and 058670'' and in its place add ''Nos. 017135 and 023851''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 6. The authority citation for part 522 continues to read as follows:

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

§ 522.84 [Removed]

■ 7. Remove § 522.84.

§ 522.518 [Removed]

■ 8. Remove § 522.518.

§ 522.1620 [Removed]

■ 9. Remove § 522.1620.

Dated: February 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03251 Filed 2–22–21; 8:45 am]

BILLING CODE 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 February 23, 2021.

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.