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]

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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.

TABLE 1—NADAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Trade name (drug)	Sponsor
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 February 23, 2021.

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.

[FR Doc. 2021–03250 Filed 2–22–21; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 201 and 202

[Docket No. 2019–4]

Group Registration of Works on an Album of Music

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: The U.S. Copyright Office is creating a new group registration option for musical works, sound recordings, and certain other works contained on an album. This option will permit the registration of a group of musical works or a group of sound recordings distributed together, regardless of whether such distribution occurs via physical or digital media. The final rule generally adopts the provisions set forth in the May 2019 notice of proposed rulemaking in this proceeding, with certain updates to reflect the planned implementation of new online applications for this option.

DATES: Effective March 26, 2021.

FOR FURTHER INFORMATION CONTACT: Regan A. Smith, General Counsel and Associate Register of Copyrights, by email at *regans@copyright.gov;* Robert Kasunic, Associate Register of Copyrights and Director of Registration Policy and Practice, by email at *rkas@copyright.gov;* or John R. Riley, Assistant General Counsel, by email at *jril@copyright.gov.* Each can be contacted by telephone at 202–707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

The Copyright Act authorizes the Register of Copyrights to specify by regulation the administrative classes of works available for the purpose of seeking a registration and the nature of the deposits required for each class. In addition, Congress gave the Register the discretion to allow registration of groups of related works with one application and one filing fee, a procedure known as ''group registration.'' [1] Pursuant to this authority, the Register has issued regulations permitting the Office to issue group registrations for certain types of works, including for groups of newspapers, unpublished works, newsletters and serials, unpublished and published photographs, contributions to periodicals, secure test items, and short online literary works.[2]

On May 20, 2019, the Office published a Notice of Proposed Rulemaking (''NPRM'') proposing to create a new group registration option for musical works, sound recordings, and associated literary, pictorial, and graphic works contained on an album. This option is referred to as ''Group Registration of Works on an Album of Music,'' or ''GRAM.'' [3] The proposed rule would allow an applicant to register up to twenty musical works and twenty sound recordings, *i.e.,* forty total works, if the works were fixed in the same phonorecord, if the works were created by the same author or had at least one common author, and if the claimant for each work in the group was the same. The proposed rule also would permit the registration of associated literary, pictorial, and graphic works in the album, such as cover art, liner notes, or posters. To exercise this option, the Office proposed that applicants would be required to submit their claims through the online copyright registration system using the Standard Application.

The Office received thirteen comments in response to the NPRM, eleven from individuals, one from the National Music Publishers Association (''NMPA''), and a joint comment by the American Association of Independent Music (''A2IM'') and the Recording Industry Association of America (''RIAA''). Each commenter supported the Office's proposal to create the new group registration option, though some suggested various amendments to the proposed rule, including removing the proposed limit on the number of works that may be included in each claim and clarifying who could be listed as a claimant of a work in a GRAM registration.

Having reviewed and carefully considered the submitted comments, the Office now issues a final rule that generally follows the proposed rule, with some modifications. First, the rule requires claims under this option to be submitted using a new online

[1] 37 CFR 202.4; *see* 17 U.S.C. 408(c)(1).

[2] 37 CFR 202.4(c)–(k).

[3] 84 FR 22762 (May 20, 2019).