removing ''061133'' and by adding in its place ''061623''.

§ 520.1720d [Amended]

12. Section 520.1720d *Phenylbutazone gel* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''No. 061623''.

§ 520.2123a [Amended]

13. Section 520.2123a *Spectinomycin dihydrochloride pentahydrate tablets* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''061623''.

§ 520.2123b [Amended]

14. Section 520.2123b *Spectinomycin dihydrochloride pentahydrate soluble powder* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''061623''.

§ 520.2260b [Amended]

15. Section 520.2260b *Sulfamethazine sustained-release boluses* is amended in paragraphs (c)(1) and (e)(1) by removing ''061133'' and by adding in its place ''061623''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

16. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.820 [Amended]

17. Section 522.820 *Erythromycin injection* is amended in paragraph (a) by removing ''061133'' and by adding in its place ''No. 061623''.

§ 522.2444b [Amended]

18. Section 522.2444b *Sodium thiopental, sodium pentobarbital for injection* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''061623''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

19. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.1580b [Amended]

20. Section 524.1580b *Nitrofurazone ointment* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''061623''.

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

21. The authority citation for 21 CFR part 526 continues to read as follows:

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

§ 526.820 [Amended]

22. Section 526.820 *Erythromycin* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''061623''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

23. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.248 [Amended]

24. Section 558.248 *Erythromycin thiocyanate* is amended in paragraphs (a)(1) and (a)(2) by removing ''061133'' and by adding in its place ''061623''; and in the table in paragraph (d)(1) in the ''Sponsor'' column by removing ''061133'' wherever it appears and by adding in its place ''061623''.

§ 558.625 [Amended]

25. Section 558.625 *Tylosin* is amended in the table in paragraph (b)(39) by removing ''061133'' and by adding in its place ''061623''.

Dated: January 6, 2003.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 03–2295 Filed 1–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Triamcinolone Spray

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by RMS Laboratories, Inc. The NADA provides for use of triamcinolone topical spray in dogs for the control of pruritus associated with allergic dermatitis.

DATES: This rule is effective January 31, 2003.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: RMS Laboratories, Inc., 1903 East First St., Vidalia, GA 30474, filed NADA 141–210 that provides for use of GENESIS (triamcinolone acetonide) Topical Spray in dogs for the control of pruritus associated with allergic dermatitis. The NADA is approved as of November 4, 2002, and the regulations are amended in part 524 (21 CFR part 524) by adding new § 524.2482 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, RMS Laboratories, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning November 4, 2002.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule 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.

List of Subjects

21 CFR Part 510

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

21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

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

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for ''RMS Laboratories, Inc.'' and in the table in paragraph (c)(2) by numerically adding an entry for ''067292'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
RMS Laboratories, Inc., 1903 East First St., Vidalia, GA 30474.	067292
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
067292	RMS Laboratories, Inc., 1903 East First St., Vidalia, GA 30474
* * * * *	

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 524 continues to read as follows:

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

4. Section 524.2482 is added to read as follows:

§ 524.2482 Triamcinolone spray.

(a) *Specifications.* Each milliliter of solution contains 0.15 milligrams triamcinolone acetonide.

(b) *Sponsor.* See No. 067292 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply sufficient pump sprays to uniformly and thoroughly wet the affected areas while avoiding run off of excess product. Administer twice daily for 7 days, then once daily for 7 days, then every other day for an additional 14 days (28 days total).

(2) *Indications for use.* For the control of pruritus associated with allergic dermatitis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: January 10, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–2211 Filed 1–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Levamisole Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of levamisole hydrochloride soluble powder in the drinking water of swine for the treatment of various internal parasites.

DATES: This rule is effective January 31, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, St. Joseph, MO 64503, filed ANADA 200–313 for Levamisole Hydrochloride Soluble Pig Wormer used to make medicated drinking water for the treatment of various internal parasites. Phoenix Scientific, Inc.'s Levamisole Hydrochloride Soluble Pig Wormer is approved as a generic copy of Schering-Plough Animal Health's TRAMISOL (levamisole hydrochloride) Soluble Pig Wormer, approved under NADA 112–049. The ANADA is approved as of October 25, 2002, and the regulations are amended in 21 CFR 520.1242a to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule 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.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.1242a is amended by adding paragraph (b)(4) to read as follows:

§ 520.1242a Levamisole hydrochloride drench and drinking water.

* * * * *

(b) * * *

(4) See No. 059130 for use of 18.15-gram packages as in paragraph (d)(3) of this section.

* * * * *

Dated: January 6, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–2212 Filed 1–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9039]

RIN 1545–BA33

Guidance Regarding the Definition of Foreign Personal Holding Company Income

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide that gain or loss arising from certain commodities