

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.

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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

hedging transactions and currency gain or loss arising from certain interest-bearing liabilities do not constitute (or are not netted against) foreign personal holding company income. This treatment is implemented because the applicable commodities hedging transactions and interest-bearing liabilities typically offset transactions that do not generate foreign personal holding company income.

DATES: Effective Date: These regulations are effective January 31, 2003.

Applicability Date: For dates of applicability, see § 1.954–2(f)(2)(iv)(C), (v)(D), and (g)(2)(ii)(C)(2)(iii).

FOR FURTHER INFORMATION CONTACT: Kenneth Christman or Gregory Spring at (202) 622–3870 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

On May 13, 2002, proposed regulations (REG–154920–01) were published in the **Federal Register** (67 FR 31995) under section 954 governing the definition of *foreign base company income* and *foreign personal holding company income* of a *controlled foreign corporation* (a CFC). These regulations addressed, among other matters, the circumstances in which income from transactions in commodities will be treated as foreign personal holding company income.

Following the publication of the proposed regulations, the IRS scheduled a public hearing and requested written comments on the regulations. The public hearing was canceled because no one requested to speak at the hearing. The IRS received one written comment, which recommended the proposed regulations be finalized as written.

Explanation of Revisions

The language of the proposed regulations is unchanged except for nonsubstantive changes to §§ 1.954–2(g)(2)(ii)(C)(2)(i) and (ii) that more explicitly set out the relationship between those paragraphs and § 1.954–2(g)(2)(ii)(C)(1).

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Therefore, a

Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal authors of these regulations are Kenneth Christman and Ted Setzer of the Office of the Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. In § 1.954–0, paragraph (b) is amended by:

1. Removing the entry for § 1.954–2(f)(2)(iii)(E).
2. Revising the entry for § 1.954–2(f)(2)(iv).
3. Adding entries for § 1.954–2(f)(2)(iv)(C), and (f)(2)(v) through (f)(2)(vi).
4. Adding entries for § 1.954–2(g)(2)(ii)(C)(1) through (g)(2)(ii)(C)(2)(iii).

The additions and revisions read as follows:

§ 1.954–0 Introduction.

* * * * *
(b) * * *

§ 1.954–2 Foreign personal holding company income.

- * * * * *
- (f) * * *
(2) * * *
(iv) Qualified hedging transaction entered into prior to January 31, 2003.
* * * * *
- (C) Effective date.
(v) Qualified hedging transaction entered into on or after January 31, 2003.
(A) In general.
(B) Exception.
(C) Examples.
(D) Effective date.
(vi) Financial institutions not a producer, etc.
(g) * * *

- (2) * * *
(ii) * * *
(C) Regular dealers.
(1) General rule.
(2) Certain interest-bearing liabilities treated as dealer property.
(i) In general.
(ii) Failure to identify certain liabilities.
(iii) Effective date.

* * * * *

Par. 3. Section 1.954–2 is amended by:

1. Removing paragraph (f)(2)(iii)(E).
 2. Revising the heading of paragraph (f)(2)(iv).
 3. Adding paragraphs (f)(2)(iv)(C) and (f)(2)(v) through (f)(2)(vi).
 4. Adding paragraphs (g)(2)(ii)(C)(1) through (g)(2)(ii)(C)(2)(iii).
 5. Revising paragraph (g)(2)(iii).
- The revisions and additions read as follows:

§ 1.954–2 Foreign personal holding company income.

* * * * *

(f) * * *
(2) * * *
(iv) *Qualified hedging transaction entered into prior to January 31, 2003.*
* * * * *

(C) *Effective date.* This paragraph (f)(2)(iv) applies to gain or loss realized by a controlled foreign corporation with respect to a qualified hedging transaction entered into prior to January 31, 2003.

(v) *Qualified hedging transaction entered into on or after January 31, 2003—(A) In general.* The term *qualified hedging transaction* means a bona fide hedging transaction, as defined in paragraph (a)(4)(ii) of this section, with respect to one or more commodities transactions reasonably necessary to the conduct of any business by a producer, processor, merchant or handler of commodities in a manner in which such business is customarily and usually conducted by others. For purposes of this paragraph (f)(2)(v), a producer, processor, merchant or handler of commodities includes a controlled foreign corporation that regularly uses commodities in a manufacturing, construction, utilities, or transportation business.

(B) *Exception.* The term *qualified hedging transaction* does not include a transaction described in section 988(c)(1) (without regard to section 988(c)(1)(D)(i)).

(C) *Examples.* The following examples illustrate the provisions of this paragraph (f)(2)(v):

Example 1. CFC1 is a controlled foreign corporation located in country A. CFC1 manufactures and sells machinery in country B using aluminum and component parts

purchased from third parties that contain significant amounts of aluminum. CFC1 conducts its manufacturing business in a manner in which such business is customarily and usually conducted by others. To protect itself against increases in the price of aluminum used in the machinery it manufactures, CFC1 enters into futures purchase contracts for the delivery of aluminum. These futures purchase contracts are bona fide hedging transactions. As CFC1 purchases aluminum and component parts containing significant amounts of aluminum in the spot market for use in its business, it closes out an equivalent amount of aluminum futures purchase contracts by entering into offsetting aluminum futures sales contracts. The aluminum futures purchase contracts are qualified hedging transactions as defined in paragraph (f)(2)(v)(A) of this section. Accordingly, any gain or loss on such aluminum futures purchase contracts is excluded from the computation of foreign personal holding company income.

Example 2. CFC2 is a controlled foreign corporation located in country B. CFC2 operates an airline business within country B in a manner in which such business is customarily and usually conducted by others. To protect itself against increases in the price of aviation fuel, CFC2 enters into forward contracts for the purchase of aviation fuel. These forward purchase contracts are bona fide hedging transactions. As CFC2 purchases aviation fuel in the spot market for use in its business, it closes out an equivalent amount of its forward purchase contracts for cash pursuant to a contractual provision that permits CFC2 to terminate the contract and make or receive a one-time payment representing the contract's fair market value. The aviation fuel forward purchase contracts are qualified hedging transactions as defined in paragraph (f)(2)(v)(A) of this section. Accordingly, any gain or loss on such aviation fuel forward purchase contracts is excluded from the computation of foreign personal holding company income.

(D) *Effective date.* This paragraph (f)(2)(v) applies to gain or loss realized by a controlled foreign corporation with respect to a qualified hedging transaction entered into on or after January 31, 2003.

(vi) *Financial institutions not a producer, etc.* For purposes of this paragraph (f), a corporation is not a producer, processor, merchant or handler of commodities if its business is primarily financial. For example, the business of a controlled foreign corporation is primarily financial if its principal business is making a market in notional principal contracts based on a commodities index.

* * * * *
(g) * * *
(2) * * *
(ii) * * *

(C) *Regular dealers—(1) General rule.* Transactions in dealer property (as defined in paragraph (a)(4)(v) of this

section) described in section 988(c)(1)(B) or (C) that are entered into by a controlled foreign corporation that is a regular dealer (as defined in paragraph (a)(4)(iv) of this section) in such property in its capacity as a dealer will be treated as directly related to the business needs of the controlled foreign corporation under paragraph (g)(2)(ii)(A) of this section.

(2) *Certain interest-bearing liabilities treated as dealer property—(i) In general.* For purposes of this paragraph (g)(2)(ii)(C), an interest-bearing liability incurred by a controlled foreign corporation that is denominated in (or determined by reference to) a non-functional currency shall be treated as dealer property of the type described in paragraph (g)(2)(ii)(C)(1) of this section if the liability, by being denominated in such currency, reduces the controlled foreign corporation's currency risk with respect to dealer property, and the liability is identified on the controlled foreign corporation's records as a liability treated as dealer property before the close of the day on which the liability is incurred.

(ii) *Failure to identify certain liabilities.* If a controlled foreign corporation identifies certain interest-bearing liabilities as liabilities treated as dealer property under paragraph (g)(2)(ii)(C)(2)(i) of this section but fails to so identify other interest-bearing liabilities that manage its currency risk with respect to assets held that constitute dealer property, the Commissioner may treat such other liabilities as properly identified as dealer property under paragraph (g)(2)(ii)(C)(2)(i) of this section if the Commissioner determines that the failure to identify such other liabilities had as one of its principal purposes the avoidance of Federal income tax.

(iii) *Effective date.* This paragraph (g)(2)(ii)(C)(2) applies only to gain or loss from an interest-bearing liability entered into by a controlled foreign corporation on or after January 31, 2003.

(iii) *Special rule for foreign currency gain or loss from an interest-bearing liability.* Except as provided in paragraph (g)(2)(ii)(C)(2) or (g)(5)(iv) of this section, foreign currency gain or loss arising from an interest-bearing liability is characterized as subpart F income and non-subpart F income in the same manner that interest expense associated with the liability would be allocated and apportioned between subpart F income and non-subpart F

income under §§ 1.861-9T and 1.861-12T.

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David A. Mader,
Assistant Deputy Commissioner of Internal Revenue.

Approved: January 17, 2003.

Pamela F. Olson,
Assistant Secretary of the Treasury.
[FR Doc. 03-2209 Filed 1-30-03; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 301 and 602

[TD 9040]

RIN 1545-AY56

Guidance Necessary To Facilitate Electronic Tax Administration

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and removal of temporary regulations.

SUMMARY: This document contains final regulations that eliminate regulatory impediments to the electronic filing of Form 1040, "U.S. Individual Income Tax Return." These regulations affect taxpayers who file Form 1040 and who are required to file any of the following forms: Form 56, "Notice Concerning Fiduciary Relationship"; Form 2120, "Multiple Support Declaration"; Form 2439, "Notice to Shareholder of Undistributed Long-Term Capital Gains"; Form 3468, "Investment Credit"; and Form T (Timber), "Forest Activities Schedules."

DATES: Effective Date: These regulations are effective January 31, 2003.

FOR FURTHER INFORMATION CONTACT: Joseph P. Dewald, (202) 622-4910 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545-1783. The collection of information in these final regulations is in §§ 1.48-12(d)(7)(iv), 1.152-3(c), 1.611-3(h), 1.852-9(c)(1), and 301.6903-1(b). Responses to this collection of information are mandatory.

An agency may not conduct or sponsor, and a person is not required to