information in the administrative record, including any submission made by the manufacturer or person. The decision of whether a cease and desist order should be issued shall be made within 30 days after receipt of any information and argument submitted by the manufacturer or person. The cease and desist order shall be final unless the affected manufacturer or person requests a reconsideration of the order to the Administrator, Agricultural Marketing Service, within 30 days after the date of the issuance of the order.

§ 1170.15 Appeals.

If the cease and desist order is confirmed by the Administrator, Agricultural Marketing Service, the manufacturer or person may appeal the order in the appropriate United States District Court not later than 30 days after the date of the confirmation of the order.

§ 1170.16 Enforcement.

(a) If a person subject to the Dairy Product Mandatory Reporting program fails to obey a cease and desist order after the order has become final and unappealable, or after the appropriate United States district court has entered a final judgment in favor of the Administrator, Agricultural Marketing Service, the United States may apply to the appropriate United States district court for enforcement of the order.

(b) If the court determines that the cease and desist order was lawfully made and duly served and that the manufacturer or person violated the order, the court shall enforce the order.

(c) If the court finds that the manufacturer or person violated the cease and desist order, the manufacturer or person shall be subject to a civil penalty of not more than $10,000 for each offense.

Dated: June 10, 2008.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E8–13550 Filed 6–16–08; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Paste

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 supplemental abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The supplemental ANADA adds effectiveness claims against various species of internal parasites when horses are treated with ivermectin paste.

DATES: This rule is effective June 17, 2008.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed a supplement to ANADA 200–326 for BIMECTIN (ivermectin) Paste 1.87% adding effectiveness claims against various species of internal parasites of horses. The supplemental ANADA is approved as of May 23, 2008, and 21 CFR 520.1192 is amended to reflect the approval.

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 Division of Dockets Management (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. In § 520.1192, remove paragraphs (b)(4) and (e)(1)(ii)(C) and revise paragraph (b)(3) to read as follows:

§ 520.1192 Ivermectin paste.

* * * * *

(b) * * *

(3) Nos. 051311, 054925, and 061623 for use of a 1.87 percent paste for use as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section.

* * * * *

Dated: June 9, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–13607 Filed 6–16–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Tylosin

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 supplemental new animal drug application (NADA) filed by Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA provides for revision of an effectiveness claim and pathogen nomenclature for a tylosin phosphate and sulfamethazine Type A medicated article used to manufacture medicated swine feeds.

DATES: This rule is effective June 17, 2008.

FOR FURTHER INFORMATION CONTACT: Timothy Schell, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8116, e-mail: *timothy.schell@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 41–275 that provides for use of TYLAN 40 SULFA–G (tylosin phosphate and sulfamethazine) Elliptical Pellets, a Type A medicated article. The

supplement provides for revision of an effectiveness claim and pathogen nomenclature. The supplemental NADA is approved as of May 8, 2008, and the regulations in 21 CFR 558.630 are amended to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

FDA 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 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 2. Revise § 558.630 to read as follows:

§ 558.630 Tylosin and sulfamethazine.

(a) *Specifications.* Type A medicated articles containing equal amounts of tylosin phosphate and sulfamethazine, available in concentrations of 4, 5, 10, 20, or 40 grams each, per pound.

(b) *Approvals.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000986: 10 or 40 grams per pound each for use as in paragraph (e)(2)(i) of this section.

(2) No. 021930: 2 grams per pound each for use as in paragraph (e)(2)(i) of this section.

(3) No. 051311: 40 grams per pound each for use as in paragraph (e)(2)(ii) of this section.

(4) No. 017139: 4, 10, or 20 grams per pound each for use as in paragraph (e)(2)(ii) of this section.

(5) Nos. 000986, 010439, 016968, 021930, 024174, 030841, 034936, 035098, 046573, 046987, and 051359: 5, 10, 20, or 40 grams per pound each for use as in paragraph (e)(2)(ii) of this section.

(6) No. 000986: 40 grams per pound each for use as in paragraph (e)(2)(iii) of this section.

(c) *Special considerations.* Labeling shall bear the statement: ''Do not use in medicated feeds containing in excess of 2% bentonite.''

(d) *Related tolerances.* See §§ 556.670 and 556.740 of this chapter.

(e) *Conditions of use.* It is used in feed for swine as follows:

(1) *Amount per ton.* 100 grams tylosin and 100 grams sulfamethazine.

(2) *Indications for use*–(i) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*); for reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E *Streptococci.* Only the sulfamethazine portion of this combination is active in controlling jowl abscesses.

(ii) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*).

(iii) For maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery associated with *Brachyspira hyodysenteriae*; and control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Arcanobacterium pyogenes*).

(3) *Limitations.* Withdraw 15 days before swine are slaughtered.

Dated: June 9, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–13606 Filed 6–16–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9401]

RIN 1545–BH33

Alternative Simplified Credit Under Section 41(c)(5)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations relating to the election and calculation of the alternative simplified credit under section 41(c)(5) of the Internal Revenue Code. The final and temporary regulations implement changes to the credit for increasing research activities under section 41 made by the Tax Relief and Health Care Act of 2006. The final and temporary regulations will affect certain taxpayers claiming credit under section 41. The text of these temporary regulations also serves as the text of the proposed regulations (REG–149405–07) published in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on June 17, 2008.

Applicability Date: For dates of applicability, see §§ 1.41–6T(j), 1.41–8T(b)(5), and 1.41–9T(d).

FOR FURTHER INFORMATION CONTACT: David A. Selig (202) 622–3040 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends 26 CFR part 1 to provide rules relating to the alternative simplified credit (ASC), which may be elected under section 41(c)(5) of the Internal Revenue Code (Code).

General Overview

Section 41(a) provides an incremental tax credit for increasing research activities (research credit), and is based on a percentage of a taxpayer's qualified research expenses (QREs) above a base amount. The Tax Relief and Health Care Act of 2006 (Pub. L. 109–432, 120 Stat. 2922, December 20, 2006) (the Act) made certain changes to the research credit, including the addition of another method of computation that taxpayers may elect to use in computing the amount of the research credit. The relevant Act provisions are effective generally for tax years after December 31, 2006, but provide certain