(January 18, 2011); Notice of August 12, 2011, 76 FR 50661 (August 16, 2011); Notice of November 9, 2011, 76 FR 70319 (November 10, 2011).

PART 745—[AMENDED]

■ 6. The authority citation for 15 CFR part 745 is revised to read as follows:

Authority: 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of November 9, 2011, 76 FR 70319 (November 10, 2011).

Dated: December 5, 2011.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2011–31687 Filed 12–8–11; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2011–N–0003]

New Animal Drugs for Use in Animal Feeds; Tilmicosin

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 use of tilmicosin Type C medicated feeds by veterinary feed directive for the control of bovine respiratory disease in groups of beef and nonlactating dairy cattle.

DATES: This rule is effective December 9, 2011.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276–8341, email: *cindy.burnsteel@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 141–064 for PULMOTIL 90 (tilmicosin phosphate) Type A medicated article. The supplemental NADA provides for the use of tilmicosin Type C medicated feeds by veterinary feed directive for the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of beef and nonlactating dairy cattle where active BRD has been diagnosed in at least 10 percent of the animals in the group. The supplemental NADA is approved as of August 19, 2011, and 21 CFR 558.4 and 558.618 are 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.

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

The Agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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.

§ 558.4 [Amended]

■ 2. In paragraph (d) of § 558.4, in the ''Category II'' table, in the ''Type B maximum (100x)'' column, in the entry for ''Tilmicosin'', remove ''18.2 g/lb (4.0%)'' and in its place add ''37.9 g/lb (8.35%)''.

■ 3. In § 558.618, revise paragraphs (a), (c), and (e) to read as follows:

§ 558.618 Tilmicosin.

(a) *Specifications.* Type A medicated article containing 90.7 grams (g) per pound tilmicosin as tilmicosin phosphate (200 g per kilogram).

* * * * *

(c) *Special considerations*—(1) Tilmicosin medicated feeds are restricted to use under a veterinary feed directive (VFD). See § 558.6 of this chapter for required label statements and other limitations.

(2) VFDs for tilmicosin phosphate shall not be refilled.

(3) Labeling of tilmicosin Type B or Type C medicated feeds must bear the following warnings:

(i) Do not allow horses or other equines access to feeds containing tilmicosin.

(ii) Use of antibacterial drugs in the absence of a susceptible bacterial infection is unlikely to provide benefit to treated animals and may increase the risk of the development of drug-resistant pathogenic bacteria.

(4) Special considerations for use of tilmicosin medicated swine feeds include the following:

(i) The expiration date of VFDs for tilmicosin must not exceed 90 days from the time of issuance.

(ii) Labeling of tilmicosin Type B or Type C medicated feeds for swine must bear the following warning: ''Do not use in any feeds containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin.''

(iii) Feed containing tilmicosin shall not be fed to pigs for more than 21 days during each phase of production without ceasing administration for reevaluation of antimicrobial use by a licensed veterinarian before reinitiating a further course of therapy with an appropriate antimicrobial.

(5) Special consideration for use of tilmicosin medicated cattle feeds include the following:

(i) The expiration date of VFDs for cattle must not exceed 45 days from the time of issuance.

(ii) Labeling of tilmicosin Type B or Type C medicated feeds for cattle must bear the following warning: ''Do not use in any feeds containing bentonite, cottonseed meal, or cottonseed hulls. Bentonite, cottonseed meal, or cottonseed hulls in feeds may affect the efficacy of tilmicosin.''

(iii) To assure both food safety and responsible use in cattle, administration of feed containing tilmicosin to cattle

experiencing an outbreak of BRD must be initiated during the first 45 days of the production period, shall not exceed a single 14-consecutive-day treatment, should not occur concurrent with or following administration of an injectable macrolide, and should not occur within 3 days following administration of a nonmacrolide injectable BRD therapy. Tilmicosin medicated feed treatment has not been evaluated in cattle with severe clinical disease. Cattle with severe clinical illness should be evaluated for individual treatment with an alternative non-macrolide therapy.

* * * * *

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

Tilmicosin phosphate in grams/ton	Indications for use	Limitations	Sponsor
(1) 181 to 363	Swine: For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.	Feed continuously as the sole ration for 21-day period, beginning approximately 7 days before an anticipated disease outbreak. The safety of tilmicosin has not been established in male swine intended for breeding purposes. Swine intended for human consumption must not be slaughtered within 7 days of the last treatment with this drug product.	000986
(2) 568 to 757	Cattle: For the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of beef and nonlactating dairy cattle, where active BRD has been diagnosed in at least 10 percent of the animals in the group.	Feed continuously for 14 days to provide 12.5 milligrams/kilogram/head/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in preruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product.	000986

Dated: December 5, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011–31613 Filed 12–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9562]

RIN 1545–BH77

Conduit Financing Arrangements

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulation.

SUMMARY: This document contains final regulations relating to conduit financing arrangements. The final regulations apply to multiple-party financing arrangements that are effected through disregarded entities, and are necessary in order to determine which of those arrangements should be recharacterized as a conduit financing arrangement.

DATES: *Effective Date:* These regulations are effective on December 9, 2011.

Applicability Date: These regulations apply to payments made on or after December 9, 2011.

FOR FURTHER INFORMATION CONTACT: Quyen P. Huynh at (202) 622–3880 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On August 10, 1995, the Department of the Treasury (Treasury Department) and the Internal Revenue Service (IRS) published final regulations under Treas. Reg. § 1.881–3 relating to conduit financing arrangements pursuant to the authority granted by section 7701(l) of the Internal Revenue Code (the conduit financing regulations). See TD 8611 (1995–37 IRB 20; 60 FR 40997). On December 22, 2008, the Treasury Department and the IRS published in the **Federal Register** (73 FR 246) a notice of proposed rulemaking (REG–113462–08) that proposed amending § 1.881–3(a)(2)(i)(C) of the conduit financing regulations to treat an entity disregarded as an entity separate from its owner for U.S. tax purposes as a person for purposes of determining whether a conduit financing arrangement exists. The proposed regulations were proposed to be effective as of the date final regulations are published in the **Federal Register**. In addition, the preamble to the proposed regulations requested comments on whether ''hybrid instruments'' (instruments treated as debt for foreign law purposes and equity for U.S. purposes) should constitute *per se* ''financing transactions'' under § 1.881–3(a)(2)(ii)(A) and part of a ''financing arrangement'' within the meaning of § 1.881–3(a)(2)(i)(A), or whether, at a minimum, certain hybrid instruments should be so treated, depending on specific factors or criteria.

Only one comment letter responding to the notice of proposed rulemaking was received. No public hearing was requested or held. After consideration of the comment, this Treasury decision adopts the proposed regulations with minor edits to *Example 3* and to clarify that the effective date of the final regulations also applies to new *Example 3.*

Explanation and Summary of Comment

The comment supported the proposed regulations and their interpretation of the term ''person'' to include a business entity that is disregarded as an entity separate from its single member owner under § 301.7701–1 through § 301.7701–3. The comment stated that to disregard an entity that is ''regarded'' for purposes of claiming treaty benefits would be inconsistent with the policy and purpose of the anti-conduit financing regulations.

As relates to hybrid instruments, the comment did not support either approach raised in the preamble to the proposed regulations, expressing both policy and administrative concerns with