Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*	*	*

* * * * *

Dated: August 2, 2004.

Linda Tollefson,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 04–18845 Filed 8–17–04; 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; Carbadox and Oxytetracycline

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 Phibro Animal Health. The NADA provides for the use of approved, single-ingredient Type A medicated articles containing carbadox and oxytetracycline to formulate two-way combination drug Type C medicated feeds for swine.

DATES: This rule is effective August 18, 2004.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov*.

SUPPLEMENTARY INFORMATION: Phibro Animal Health, 710 Rt. 46 East, suite 401, Fairfield, NJ 07004, filed NADA 141–211 that provides for the use of MECADOX (carbadox), approved under NADA 41–061, and TERRAMYCIN (oxytetracycline) Type A medicated articles, approved under NADA 95–143, to formulate two-way combination drug Type C medicated feeds for swine. The Type C medicated feeds are used for treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline, for treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency. The application is approved as of July 21, 2004, and the regulations are amended in 21 CFR 558.115 and 558.450 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 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)(2) 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. Section 558.115 is amended by adding paragraph (d)(4) to read as follows:

§ 558.115 Carbadox.

* * * * *

(d) * * *

(4) *Amount.* Carbadox, 10 to 25 grams per ton of feed; plus oxytetracycline, 10 milligrams per pound of body weight.

(i) *Indications for use.* For treatment of bacterial enteritis caused by *Escherichia coli* and *S. choleraesuis* susceptible to oxytetracycline, for treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Feed continuously for 7 to 14 days. Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

■ 3. Section 558.450 is amended by redesignating paragraph (d)(3)(i) as paragraph (d)(3)(iv); and by adding new paragraph (d)(3)(i) to read as follows:

§ 558.450 Oxytetracycline.

* * * * *

(d) * * *

(3) * * *

(i) Carbadox as in § 558.115 of this chapter.

* * * * *

Dated: August 2, 2004.

Linda Tollefson,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 04–18844 Filed 8–17–04; 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; Ractopamine

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 two new animal drug applications (NADAs) filed by Elanco Animal Health. One NADA provides for use of ractopamine, melengestrol, and monensin Type A medicated articles to make three-way combination Type C medicated feeds for heifers fed in confinement for slaughter. The other NADA provides for use of ractopamine, melengestrol, monensin, and tylosin Type A medicated articles to make four-way combination Type C medicated feeds for heifers fed in confinement for slaughter.

DATES: This rule is effective August 18, 2004.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141–234 that provides for use of OPTAFLEXX (ractopamine hydrochloride), MGA (melengestrol acetate), and RUMENSIN (monensin sodium) Type A medicated articles to make three-way combination Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for suppression of estrus (heat) in heifers fed in confinement for slaughter during the last 28 to 42 days on feed. Elanco Animal Health also filed NADA 141–233 that provides for use of OPTAFLEXX, MGA, RUMENSIN, and TYLAN (tylosin phosphate) Type A medicated articles to make four-way combination Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*; for suppression of estrus (heat); and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces* (*Corynebacterium*) *pyogenes* in heifers fed in confinement for slaughter during the last 28 to 42 days on feed. The NADAs are approved as of July 2, 2004, and the regulations in 21 CFR 558.342, 558.355, 558.500, and 558.625 are amended to reflect the approvals. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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)(2) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor environmental impact statement is required for either.

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 the 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. Section 558.342 is amended by adding paragraph (e)(2) to read as follows:

§ 558.342 Melengestrol.

* * * * *

(e) * * *

(2) Melengestrol may also be used with ractopamine alone or in combination as in § 558.500 of this chapter.

§ 558.355 [Amended]

■ 3. Section 558.355 is amended in paragraph (f)(7)(iii) by removing ''with tylosin'' and by adding in its place ''in combination''.

■ 4. Section 558.500 is amended by adding paragraphs (e)(2)(viii) and (e)(2)(x) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

* * * * *

(2) *Cattle*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	* *	*	* *	*
(viii) 9.8 to 24.6	Monensin 10 to 30, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for suppression of estrus (heat).	As in paragraph (e)(2)(vi) of this section; see §§ 558.342(d) and 558.355(d) of this chapter. Melengestrol acetate as provided by No. 000009 in § 510.600(c) of this chapter.	000986

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	* *	*	* *	*
(x) 9.8 to 24.6	Monensin 10 to 30, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*; and for suppression of estrus (heat).	As in paragraph (e)(2)(vi) of this section; see §§ 558.342(d), 558.355(d), and 558.625(c) of this chapter. Melengestrol acetate as provided by No. 000009 in § 510.600(c) of this chapter.	000986

§ 558.625 [Amended]

■ 5. Section 558.625 is amended in paragraph (f)(2)(vii) by removing ''with monensin'' and by adding in its place ''in combination''.

Dated: July 27, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04–18843 Filed 8–17–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9155]

RIN 1545–BD58

Guidance Under Section 1502; Treatment of Loss Carryovers From Separate Return Limitation Years

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations under section 1502 that provide guidance regarding the treatment of certain losses available to acquired subsidiaries as a result of an election made under the section 1502 regulations. The text of these temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**. These regulations apply to corporations filing consolidated returns.

DATES: *Effective Date:* These regulations are effective August 18, 2004.

Applicability Date: For dates of applicability see § 1.1502–32T(b)(4)(v)(C).

FOR FURTHER INFORMATION CONTACT: Sean McKeever at (202) 622–7750 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Under § 1.1502–32(b)(4), if a subsidiary of a consolidated group has a loss carryover from a separate return limitation year when it becomes a member of the group, the group may make an irrevocable election to treat all or any portion of the loss carryover as expiring for all Federal income tax purposes immediately before the subsidiary becomes a member of the group. If the subsidiary was a member of another group immediately before it became a member of the group, the expiration is also treated as occurring immediately after it ceases to be a member of the prior group. Waiving losses of an acquired subsidiary is desirable in cases in which it is anticipated that the losses of the subsidiary may expire unused in that it prevents a negative basis adjustment in the stock of the subsidiary.

In March of 2002, in response to the decision of the United States Court of Appeals for the Federal Circuit in *Rite Aid Corp.* v. *United States,* 255 F.3d 1357 (Fed. Cir. 2001), the Treasury Department and the IRS issued guidance regarding the treatment of certain losses realized on dispositions and deconsolidations of stock of a member of a consolidated group. Those rules permitted groups to calculate allowable loss on the sale of subsidiary stock by applying § 1.1502–20 in its entirety, § 1.1502–20 without regard to the duplicated loss factor of the loss disallowance formula, or § 1.337(d)–2T. If a group that made an election described in § 1.1502–20(g) to reattribute to the common parent losses of the subsidiary elected to determine allowable loss by applying either § 1.1502–20 without regard to the duplicated loss factor of the loss disallowance formula, or § 1.337(d)–2T, the amount of loss treated as reattributed could be reduced. As a result, losses that were previously treated as reattributed would be treated as available for use by the subsidiary or any other group of which the subsidiary is a member, subject to any applicable limitations (*e.g.*, section 382). To prevent a purchasing consolidated group from being unfairly disadvantaged in the event that the amount of losses treated as reattributed to the common parent of the selling group were decreased and the amount of losses treated as available to the subsidiary were increased (excess losses), § 1.1502–32T(b)(4)(v) was added to provide that, to the extent that the subsidiary's loss carryovers are increased by reason of an election to apply one of the alternative regimes and such loss carryovers expire, or would have been properly used to offset income, in a closed year, the purchasing group will be deemed to have made an election to treat all of such expired loss carryovers as expiring for all Federal income tax purposes immediately before the subsidiary became a member of the purchasing group (the deemed waiver rule). Accordingly, no basis reduction under § 1.1502–32 would result from the expiration of, or failure to use, such losses.

The Treasury Department and the IRS have become aware that the deemed waiver rule may deny the use of excess losses in cases in which such denial was