List of Subjects in 20 CFR Part 341

Railroad unemployment insurance, Reporting and recordkeeping requirements.

■ For the reasons set out in the preamble, the Railroad Retirement Board amends title 20, Chapter II, subchapter C, part 341 of the Code of Federal Regulations as follows:

PART 341—STATUTORY LIEN WHERE SICKNESS BENEFITS PAID

■ 1. The authority citation for part 341 continues to read as follows:

Authority: 45 U.S.C. 362(o).

■ 2. Revise § 341.6(a) introductory text to read as follows:

§ 341.6 Report of settlement or judgment.

(a) When a person or company makes a settlement or must satisfy a final judgment based on an injury for which the employee received sickness benefits, the person or company shall notify the Board of the settlement or final judgment. That notice shall be in writing and submitted within five days of the settlement or final judgment. A railroad employer may fulfill the written notice requirement by sending an electronic message in the manner prescribed by the agency. That notification shall contain:

* * * * *

■ 3. Amend § 341.8 as follows:

■ a. Add a new sentence to the end of paragraph (a);

■ b. Revise paragraph (b); and

■ c. Amend paragraph (c) by removing the phrase ''Division of Claims Operations'' and adding the phrase ''Sickness and Unemployment Benefits Section'' in its place.

■ The additions and revisions read as follows:

§ 341.8 Termination of sickness benefits due to a settlement.

(a) * * * A railroad employer may file the required report by sending an electronic message in the manner prescribed by the agency.

(b) A report of settlement shall be made to the Sickness and Unemployment Benefits Section and shall include the information required in § 341.6. Where the report is an oral report, and the informant is neither the employee nor his or her representative, the informant shall be told that written confirmation containing the information called for by § 341.6 must be submitted to the Board within 5 days from the date of the oral report. A railroad employer may fulfill the written report requirement by sending an electronic message in the manner prescribed by the agency.

* * * * *

Dated: September 5, 2006.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. E6–14884 Filed 9–7–06; 8:45 am]

BILLING CODE 7905–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs; Zilpaterol

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 Intervet Inc. The NADA provides for use of a zilpaterol hydrochloride Type A medicated article to formulate Type B and Type C medicated feeds for cattle fed in confinement for slaughter.

DATES: This rule is effective September 8, 2006.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–120), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301 827–1600, e-mail: *eric.dubbin@.fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed NADA 141–258 for the oral use of ZILMAX (zilpaterol hydrochloride 4.8%) Type A medicated article to formulate Type B (liquid and dry) and Type C medicated cattle feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed. The NADA is approved as of August 10, 2006, and the regulations are amended in part 556 (21 CFR part 556) and part 558 (21 CFR part 558) by adding new §§ 556.765 and 558.665 and by amending § 558.4 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 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 between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning August 10, 2006.

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 556

Animal drugs, Foods.

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 parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 2. Add § 556.765 to read as follows:

§ 556.765 Zilpaterol.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of zilpaterol is 0.083 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for zilpaterol freebase (the marker residue) is 12 parts per billion (ppb).

(ii) [Reserved]

(2) [Reserved]

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 4. In paragraph (d) of § 558.4, in the ''Category II'' table, alphabetically add an entry for ''Zilpaterol'' to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY II

Drug	Assay limits percent[1] Type A	Type B maximum (100x)	Assay limits percent[1] Type B/C[2]
*	*	*	*
Zilpaterol	90–110	680 g/t (0.075%)	80–110/75–115

[1]Percent of labeled amount.

[2]Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

* * * * *

■ 5. Add § 558.665 to read as follows:

§ 558.665 Zilpaterol.

(a) *Specifications.* Type A medicated articles containing 21.77 grams (g) zilpaterol hydrochloride per pound.

(b) *Approvals.* See No. 057926 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.765 of this chapter.

(d)*Special considerations*—(1) Labeling of Type B and Type C cattle feeds shall bear the following:

(i) Do not allow horses or other equines access to feed containing zilpaterol.

(ii) Not for use in animals intended for breeding.

(iii) Do not use in veal calves.

(2) Type B Liquid Feeds can be manufactured containing 68 to 680 g zilpaterol hydrochloride/ton. The liquid Type B feeds must be maintained at a pH of 3.8 to 7.5. For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used. For liquid feeds stored in mechanical, air or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(3) Do not pellet medicated feeds containing zilpaterol.

(e) *Conditions of use in cattle*—(1) *Amount.* 6.8 g/ton of feed to provide 60 to 90 milligrams zilpaterol hydrochloride per head per day.

(2) *Indications for use.* For increased rate of weight gain, improved feed efficiency and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.

(3) *Limitations.* Feed continuously as the sole ration during the last 20 to 40 days on feed. Withdrawal period: 3 days.

Dated: August 29, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–14899 Filed 9–7–06; 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 Feed; 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 supplemental new animal drug application (NADA) filed by Phibro Animal Health. The supplemental NADA revises labeling of oxytetracycline Type A medicated article with the current genus for the causative bacteria for American foulbrood of honeybees.

DATES: This rule is effective September 8, 2006.

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.hhs.gov*.

SUPPLEMENTARY INFORMATION: Phibro Animal Health, 65 Challenger Rd., 3d floor, Ridgefield Park, NJ 07660, filed a supplement to NADA 95–143 that provides for use of TERRAMYCIN 100MR (oxytetracycline dihydrate) Type A medicated article for treatment of various bacterial diseases of livestock. The supplemental NADA revises labeling with the current genus for the causative bacteria for American foulbrood of honeybees. The supplemental NADA is approved as of August 11, 2006, and the regulations in 21 CFR 558.450 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 § 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.

§ 558.450 [Amended]

■ 2. In § 558.450, in the table in paragraph (d)(1)(xiv) in the ''Indications for use'' column, remove ''*Bacillus*'' and add in its place ''*Paenibacillus*''.