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[FR Doc. E7–23840 Filed 12–12–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; 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 Pennfield Oil Co. that provides for a zero-day preslaughter withdrawal time following use of oxytetracycline in turkey and swine feed.

DATES: This rule is effective December 13, 2007.

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: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, filed a supplement to NADA 138–938 for PENNOX (oxytetracycline) Type A medicated articles used for making medicated feeds for the treatment of various bacterial diseases of livestock and fish. The supplemental NADA provides for a zero-day withdrawal time prior to slaughter when Type C medicated feeds containing oxytetracycline are fed to turkeys or swine and for minor label revisions. The supplemental application is approved as of November 26, 2007, and the regulations are amended in 21 CFR 558.450 to reflect the approval, an editorial change, and a current format.

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)(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. In § 558.450, revise paragraphs (a)(1), (a)(2), (b)(3), and (d) to read as follows:

§ 558.450 Oxytetracycline.

(a) * * *

(1) 10, 20, 30, 50, 100, and 200 grams per pound to No. 066104 in § 510.600(c) of this chapter.

(2) 50, 100, and 200 grams per pound to No. 048164 in § 510.600(c) of this chapter.

(b) * * *

(3) 50-, 100-, and 200-gram per pound articles in paragraph (a)(2) of this section contain oxytetracycline dihydrate expressed in terms of an equivalent amount of oxytetracycline hydrochloride. Another 100-gram per pound article in paragraph (a)(2) of this section contains oxytetracycline hydrochloride.

* * * * *

(d) *Conditions of use*—(1) *Chickens*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 grams per ton (g/ton)	Chickens: For increased rate of weight gain and improved feed efficiency.	Feed continuously; do not feed to chickens producing eggs for human consumption.	066104, 048164
(ii) 100 to 200 g/ton	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae* and control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days (d); do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter.	066104, 048164
(iii) 400 g/ton	Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter.	066104, 048164
(iv) 500 g/ton	Chickens: For reduction of mortality due to air sacculitis (air sac infection) caused by *E. coli* susceptible to oxytetracycline.	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds, withdraw 3 d before slaughter.	066104, 048164

(2) *Turkeys*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Growing turkeys: For increased rate of weight gain and improved feed efficiency.	Feed continuously; do not feed to turkeys producing eggs for human consumption.	066104, 048164

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(ii) 100 g/ton	Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	066104, 048164
(iii) 200 g/ton	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; for No. 066104 withdraw 5 d before slaughter; for No. 048164 zero-day withdrawal time; do not feed to turkeys producing eggs for human consumption.	066104, 048164
(iv) 25 milligrams/pound (mg/lb) of body weight daily	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; for No. 066104 withdraw 5 d before slaughter; for No. 048164 zero-day withdrawal time; do not feed to turkeys producing eggs for human consumption.	066104, 048164

(3) *Swine*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Swine: For increased rate of weight gain and improved feed efficiency.	Feed continuously.	066104, 048164
(ii) 10 mg/lb of body weight daily	1. Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d.	066104, 048164
	2. Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline.	Feed continuously for 14 d.	066104, 048164

(4) *Cattle*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 0.05 to 0.1 mg/lb of body weight daily	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency.	Feed continuously in milk replacer or starter feed.	066104, 048164
(ii) 10 mg/lb of body weight daily	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; for No. 048164, withdraw 5 d before slaughter; for No. 066104, zero-day withdrawal time.	066104, 048164
	2. Calves: For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d in milk replacer or starter feed; for No. 048164, withdraw 5 d before slaughter; for No. 066104, zero-day withdrawal time.	066104, 048164
(iii) 25 mg/head/day	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency.	Feed continuously.	066104, 048164
(iv) 75 mg/head/day	Growing cattle (over 400 lb): For increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.	Feed continuously.	066104, 048164
(v) 0.5 to 2.0 g/head/day	Cattle: For prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 d before and after arrival in feedlots.	066104, 048164

(5) *Minor species*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 20 g/ton	Sheep: For increased rate of weight gain and improved feed efficiency.	Feed continuously.	066104, 048164

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(ii) 10 mg/lb of body weight daily	Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.	066104, 048164
(iii) 200 mg/colony	Honey bees: For control of American foulbrood caused by *Paenibacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline.	Remove at least 6 weeks prior to main honey flow.	066104, 048164
(iv) 250 mg/kilogram of fish/day (11.35 g/100 lb of fish/day)	Pacific salmon: For marking of skeletal tissue.	For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days; fish not to be liberated for at least 7 d following the last administration of medicated feed.	066104
(v) 2.5 to 3.75 g/100 lb of fish/day	1. Salmonids: For control of ulcer disease caused by *Hemophilus piscium*, furunculosis caused by *Aeromonas salmonicida*, bacterial hemorrhagic septicemia caused by *A. liquefaciens*, and pseudomonas disease. 2. Catfish: For control of bacterial hemorrhagic septicemia caused by *A. liquefaciens* and pseudomonas disease.	Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 9 °C (48.2 °F). Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 16.7 °C (62 °F).	066104 066104
(vi) 1 g/lb of medicated feed	Lobsters: For control of gaffkemia caused by *Aerococcus viridans*.	Administer as sole ration for 5 consecutive days; withdraw medicated feed 30 d before harvesting lobsters.	066104

(6) Oxytetracycline may be used in accordance with the provisions of this section in the combinations as follows:

(i) Carbadox as in § 558.115.

(ii) Lasalocid as in § 558.311.

(iii) Melengestrol acetate as in § 558.342.

(iv) Robenidine hydrochloride as in § 558.515.

(v) Salinomycin as in § 558.550.

Dated: December 5, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–24146 Filed 12–12–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; 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 a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for an increased level of monensin in three-way combination Type C medicated feeds containing ractopamine, melengestrol, and monensin for heifers fed in confinement for slaughter.

DATES: This rule is effective December 13, 2007.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@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 141–234 that provides for use of OPTAFLEXX (ractopamine hydrochloride), MGA (melengestrol acetate), and RUMENSIN (monensin USP) Type A medicated articles to make dry and liquid 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. The supplemental NADA provides for an increased level of monensin. The supplemental NADA is approved as of November 20, 2007, and the regulations in 21 CFR 558.500 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.

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 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 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: