§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Church & Dwight Co., Inc., 469 North Harrison St., Princeton, NJ 08543–5297	010237
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
010237	Church & Dwight Co., Inc., 469 North Harrison St., Princeton, NJ 08543–5297
* * * * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.580 [Amended]

4. Section 520.580 *Dichlorophene and toluene capsules* is amended by removing footnote 1 every place it appears in the section and in paragraph (b)(1) by removing ''011615'' and by adding in its place ''010237''.

5. Section 520.2043 is revised to read as follows:

§ 520.2043 Pyrantel pamoate suspension.

(a) *Specifications.* (1) Each milliliter (mL) contains pyrantel pamoate equivalent to 50 milligrams (mg) pyrantel base.

(2) Each mL contains pyrantel pamoate equivalent to 2.27 or 4.54 mg pyrantel base.

(3) Each mL contains pyrantel pamoate equivalent to 4.54 mg pyrantel base.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) Nos. 000069 and 059130 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(2) Nos. 000069, 010237, and 059130 for use of the products described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(3) No. 023851 for use of the product described in paragraph (a)(3) as in paragraph (d)(2) of this section.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use*—(1) *Horses and ponies.* It is used as follows:

(i) *Amount.* 3 mg per pound (/lb) body weight as a single dose mixed with the usual grain ration, or by stomach tube or dose syringe.

(ii) *Indications for use.* For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*), small strongyles, pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(iii) *Limitations.* Not for use in horses and ponies to be slaughtered for food purposes. When the drug is for administration by stomach tube, it shall be labeled: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(2) *Dogs.* It is used as follows:

(i) *Dogs and puppies*—(A) *Amount.* 2.27 mg/lb body weight as a single dose in the animal's feed bowl by itself or mixed in a small quantity of food.

(B) *Indications for use.* For the removal of large roundworms (*Toxocara canis* and *Toxascarias leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(C) *Limitations.* Additional treatment may be required and should be confirmed by fecal examination within 2 to 4 weeks.

(ii) *Dogs, puppies, and lactating bitches after whelping*—(A) *Amount.* 2.27 mg/lb body weight.

(B) *Indications for use.* To prevent reinfections of *T. canis.*

(C) *Limitations.* Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals.

Dated: May 24, 2002.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 02–16050 Filed 6–26–02; 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; Chlortetracycline

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 Alpharma, Inc. The supplemental NADA provides for the administration of Type C medicated feeds containing chlortetracycline to cattle as a top dress on feed for the treatment of enteritis and pneumonia.

DATES: This rule is effective June 27, 2002.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 48–761 for AUREOMYCIN 50, 90, or 100 (chlortetracycline) Type A medicated articles. The supplemental NADA provides for the administration of Type C medicated feeds containing chlortetracycline to calves, beef and nonlactating dairy cattle as a top dress on feed to deliver 10 milligrams (mg) chlortetracycline per pound of body weight daily. These medicated feeds are used for the treatment of bacterial enteritis caused by *Escherichia coli* and

bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline. The supplemental NADA is approved as of January 24, 2002, and the regulations are amended in 21 CFR 558.128 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 558.128 is also being amended to relocate a recently assigned withdrawal time (64 FR 23539, May 3, 1999) to the ''Limitations'' column of the table describing conditions of use. This is being done to improve the readability of the regulations.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (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 approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning January 24, 2002, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval and conducted or sponsored by the applicant.

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. Section 558.128 is amended by redesignating paragraphs (a), (b), and (d) as paragraphs (b), (c), and (e), respectively; by adding new paragraphs (a) and (d); and by revising newly redesignated paragraphs (b) and (e) to read as follows:

§ 558.128 Chlortetracycline.

(a) *Specifications.* Type A medicated articles containing either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride or, for products intended for use in milk replacer, chlortetracycline hydrochloride.

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

(1) Nos. 046573, 053389, and 066104: 50 to 100 grams per pound (g/lb) of Type A medicated article.

(2) No. 017519: 50 g/lb of Type A medicated article.

* * * * *

(d) *Special considerations.* (1) In milk replacers or starter feed; include on labeling the warning: ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.''

(2) Manufacture for use in free-choice feeds as in paragraph (e)(4)(iii) of this section must conform to § 510.455 of this chapter.

(3) When manufactured for use as in paragraph (e)(5)(iv) of this section, include on labeling the warning: ''Psittacosis, avian chlamydiosis, or ornithosis is a reportable communicable disease, transmissible between wild and domestic birds, other animals, and man. Contact appropriate public health and regulatory officials.''

(e) Conditions of use—(1) *Chickens.* It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Chickens: For increased rate of weight gain and improved feed efficiency.	. . . . . . Do not feed to chickens producing eggs for human consumption.	046573. 017519, 046573, 053389, 066104.
(ii) 100 to 200 g/ton	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	1. Feed continuously for 7 to 14 d. 2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	046573. 017519, 046573, 053389, 066104.
(iii) 200 to 400 g/ton	Chickens: For the control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.	1. Feed continuously for 7 to 14 d. 2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	046573. 017519, 046573, 053389, 066104.
(iv) 500 g/ton	Chickens: For the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.	1. Feed for 5 d. 2. Feed for 5 d; do not feed to chickens producing eggs for human consumption.	046573. 017519, 046573, 053389, 066104.

(2) *Turkeys*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Growing turkeys: For increased rate of weight gain and improved feed efficiency.	Do not feed to turkeys producing eggs for human consumption.	017519, 046573, 053389, 066104.
(ii) 200 g/ton	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	017519, 046573, 053389, 066104.
(iii) 400 g/ton	1. Turkeys: For control of hexamitiasis caused by *Hexamita meleagrides* susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	017519, 046573, 053389, 066104.
	2. Turkey poults not over 4 weeks of age: For reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.		017519, 046573, 053389, 066104.
(iv) 25 mg/lb of body weight	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	017519, 046573, 053389, 066104.

(3) *Swine*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Growing swine: For increased rate of weight gain and improved feed efficiency.		017519, 046573, 053389, 066104.
(ii) 50 to 100 g/ton	Swine: For reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group *E. Streptococci* susceptible to chlortetracycline.		017519, 046573, 053389, 066104.
(iii) 400 g/ton	Breeding swine: For the control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to chlortetracycline.	Feed continuously for not more than 14 d.	017519, 046573, 053389, 066104.
(iv) 10 mg/lb of body weight	1. Swine: For the treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.	Feed approximately 400 g/t, varying with body weight and feed consumption to provide 10 mg/lb per day. Feed for not more than 14 d; withdraw 5 d prior to slaughter for sponsor 017519.	017519, 046573, 053389, 066104.
	2. Swine: For the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.	Feed for not more than 14 d.	046573.

(4) *Cattle*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 0.1 mg/lb of body weight daily.	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency.	See paragraph (d)(1) of this section.	017519, 046573, 053389, 066104.
(ii) 0.5 mg/lb of body weight daily.	Beef cattle (over 700 lb); control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. To sponsor No. 046573: zero withdrawal time. To sponsor No. 053389: 1 d withdrawal time.	017519, 046573, 053389, 066104.

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(iii) 0.5 to 2.0 mg/lb of body weight daily.	Beef cattle and nonlactating dairy cattle: As an aid in the control of active infection of anaplsmosis caused by *A. marginale* susceptible to chlortetracycline.	In free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles. See paragraph (d)(2) of this section.	046573.
(iv) 10 mg/lb of body weight daily.	1. Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 d; in feed including milk replacers; withdraw 10 d prior to slaughter. To sponsor No. 053389: 1 d withdrawal time. To sponsor No. 046573: zero withdrawal time. See paragraph (d)(1) of this section.	017519, 046573, 053389, 066104.
	2. Calves (up to 250 lb): For the treatment of bacterial enteritis caused by *E. coli* susceptible to chlortetracycline.	See paragraph (d)(1) of this section.	017519, 046573, 053389, 066104.
(v) 4,000 to 20,000 g/ton	Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	As a top dress, varying with body weight and feed consumption, to provide 10 mg/lb per day. Treat for not more than 5 days. See paragraph (d)(1) of this section.	046573.
(vi) 25 to 70 mg/head/day	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency.	See paragraph (d)(1) of this section.	017519, 046573, 053389, 066104.
(vii) 70 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.	See paragraph (d)(1) of this section.	017519, 046573, 053389, 066104.
(viii) 350 mg/head/day	1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella*spp. susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. For sponsor 046573: zero withdrawal time. For sponsor 053389: 1 d withdrawal time.	017519, 046573, 053389, 066104.
	2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. For sponsor 046573: zero withdrawal time. For sponsor 053389: 1 d withdrawal time.	017519, 046573, 053389, 066104.

(5) *Minor species.* It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 20 to 50 g/ton	Growing sheep; increased rate of weight gain and improved feed efficiency.		046573, 053389, 066104.
(ii) 80 mg/head/day	Breeding sheep; reducing the incidence of (vibrionic) abortion caused by *Campylobacter fetus* infection susceptible to chlortetracycline.		046573, 053389, 066104.
(iii) 200 to 400 g/ton	Ducks: For the control and treatment of fowl cholera caused by *P. multocida* susceptible to chlortetracycline.	Feed in complete ration to provide from 8 to 28 mg/lb of body weight per day depending upon age and severity of disease, for not more than 21 d. Do not feed to ducks producing eggs for human consumption.	046573.

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(iv) 10 mg/g of finished feed daily.	Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by *Chlamydia psittaci* sensitive to chlortetracycline.	Feed continuously for 45 d; each bird should consume daily an amount of medicated feed equal to one fifth of its body weight. See paragraph (d)(3) of this section.	046573.

(6) *Chlortetracycline*. It may be used in accordance with this section in combinations as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium plus ethopabate in accordance with § 558.58.

(iii) Bacitracin methylene disalicylate in accordance with § 558.76.

(iv) Clopidol in accordance with § 558.175.

(v) Decoquinate in accordance with § 558.195.

(vi) Hygromycin B in accordance with § 558.274.

(vii) Monensin in accordance with § 558.355.

(viii) Robenidine hydrochloride in accordance with § 558.515.

(ix) Roxarsone in accordance with § 558.530.

(x) Salinomycin alone or with roxarsone in accordance with § 558.550.

(xi) Tiamulin in accordance with § 558.600.

(xii) Zoalene in accordance with § 558.680.

Dated: May 29, 2002.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 02–16161 Filed 6–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 3

[USCG–2002–12471]

RIN 2115–AG44

Navigation and Navigable Waters—Technical Amendments, Organizational Changes, Miscellaneous Editorial Changes and Conforming Amendments; Delay of Effective Date for Certain Amendments Relating to the Marine Inspection Zones and Captain of the Port Zones for Hampton Roads and Wilmington (NC)

AGENCY: Coast Guard, DOT.

ACTION: Final rule; delay of effective date for certain amendments.

SUMMARY: We are revising the effective date of two sections of a technical amendments rule published June 18, 2002, that will become effective June 28, 2002. That rule makes technical and organizational amendments to Coast Guard navigation and navigable waters regulations. The two sections of the rule that revise the boundaries between Hampton Roads Marine Inspection/Captain of the Port Zone and the Wilmington Marine Inspection/Captain of the Port Zone, will not become effective until October 1, 2002. This rule changes the effective date for just those two sections.

DATES: The effective date for the revisions to 33 CFR 3.25–10(b) and 3.25–20(b), published at 67 FR 41331, June 18, 2002, is delayed from June 28, 2002, until October 1, 2002.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Robert Spears, Project Manager, Standards Evaluation and Development Division, (G–MSR–2), Coast Guard, at 202–267–1099. If you have questions on viewing, or submitting material to the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, at 202–366–5149.

SUPPLEMENTARY INFORMATION: On June 18, 2002, in Volume 67 of **Federal Register** Number 117, pages 41329–41334, the Coast Guard published a final rule entitled ''Navigation and Navigable Waters—Technical Amendments, Organizational Changes, Miscellaneous Editorial Changes and Conforming Amendments.'' The final rule made editorial and technical changes throughout title 33 of the Code of Federal Regulations (CFR) to update the title before recodification on July 1, 2002. The final rule updated organization names and addresses, and made conforming amendments and technical corrections.

Two revisions changed the boundaries between the Hampton Roads Marine Inspection/Captain of the Port Zone (33 CFR 3.25–10(b)) and the Wilmington Marine Inspection/Captain of the Port Zone (33 CFR 3.25–20(b)) (67 FR 41331). We anticipate that Coast Guard Marine Safety Office Wilmington will have a fully staffed, operation-ready detachment in place to serve the public in this new area of responsibility by September 2002. Therefore, we are making the revisions to 33 CFR 3.25–10(b) and 33 CFR 3.25–20(b) effective October 1, 2002.

Dated: June 21, 2002.

Joseph J. Angelo,

Director of Standards, Marine Safety, Security and Environmental Protection.

[FR Doc. 02–16237 Filed 6–26–02; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD07–02–070]

Drawbridge Operation Regulations; Atlantic Intracoastal Waterway, Mile 1074.0 at Hallandale Beach, Broward County, FL

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Seventh Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the New Hallandale Beach Boulevard bridge, mile 1074.0 at Hallandale Beach, Florida. This deviation allows this bridge to only open a single-leaf from July 1, 2002, to August 29, 2002. This action is necessary to facilitate workers' safety during construction of the new bridge.

DATES: This deviation is effective from 12:01 a.m. on July 1, 2002, until 11 p.m. on August 29, 2002.

ADDRESSES: Material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 SE. 1st Avenue, Room 432, Miami, FL 33131 between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Lieberum, Project Officer,