DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; 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 five supplemental new animal drug applications (NADA's) filed by the following sponsors:

- Hoffmann-LaRoche, Inc., Nutley, NJ 07110 (formerly held by American Cyanamid Co.), to NADA 92-286, which covers the Type A medicated articles: Aureomix® 293 (50 grams of chlorotetracycline hydrochloride per pound (g CTC HCl/lb)) and Aureomycin® 50, 70, 80, 90, and 100 (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- Pfizer, Inc., 235 East 42d St., New York, NY 10017, to NADA 92-286, which covers the Type A medicated articles CLTC® 10, 20, 30, 50, and 70 (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl); and
- ALPHARMA, Inc. (formerly A. L. Laboratories), One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, to NADA 46-699, which covers the Type A medicated articles: CTC 100 MR (100 g CTC HCl/lb) and CTC 10, CTC 50, CTC 65, CTC 70, and Micro CTC 100 (contains CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- ADM Animal Health & Nutrition Div., P.O. Box 2508, Fort Wayne, IN 46801-2508 (formerly Feed Specialties Co., Inc.), to NADA 48-480, which covers the Type A medicated article Chloratet® 50 (contains CTC calcium complex equivalent to 50 g CTC HCl/lb); and
- PennField Oil Co., 14040 Industrial Rd., Omaha, NE 68137, to NADA 138-935, which covers the Type A medicated articles: Chlorotetramycin Premixes 50, 60, 70, 80, 100 (all contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl), and 100 MR (100 g CTC HCl/lb).

The supplementary NADA's provide for approval of five supplemental new animal drug applications (NADA's) filed by the following sponsors:

- Hoffmann-LaRoche, Inc., Nutley, NJ 07110 (formerly held by American Cyanamid Co.), to NADA 92-286, which covers the Type A medicated articles: Aureomix® 293 (50 grams of chlorotetracycline hydrochloride per pound (g CTC HCl/lb)) and Aureomycin® 50, 70, 80, 90, and 100 (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- Pfizer, Inc., 235 East 42d St., New York, NY 10017, to NADA 92-286, which covers the Type A medicated articles CLTC® 10, 20, 30, 50, and 70 (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl); and
- ALPHARMA, Inc. (formerly A. L. Laboratories), One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, to NADA 46-699, which covers the Type A medicated articles: CTC 100 MR (100 g CTC HCl/lb) and CTC 10, CTC 50, CTC 65, CTC 70, and Micro CTC 100 (contains CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- ADM Animal Health & Nutrition Div., P.O. Box 2508, Fort Wayne, IN 46801-2508 (formerly Feed Specialties Co., Inc.), to NADA 48-480, which covers the Type A medicated article Chloratet® 50 (contains CTC calcium complex equivalent to 50 g CTC HCl/lb); and
- PennField Oil Co., 14040 Industrial Rd., Omaha, NE 68137, to NADA 138-935, which covers the Type A medicated articles: Chlorotetramycin Premixes 50, 60, 70, 80, 100 (all contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl), and 100 MR (100 g CTC HCl/lb).

The drug products were the subject of NAS/NRC DESI evaluation is concerned only with the drugs' effectiveness and safety to the treated animal. It does not take into account the safety for food use of food derived from drug-treated animals. Nothing herein will constitute a bar to further proceedings with respect to questions of safety of the drugs or their metabolites in foods produced derived from treated animals.

The five subject sponsors filed supplements that revised the labeling of their products to comply with the findings of the NAS/NRC review and FDA's conclusions concerning those findings. The supplemental NADA's were approved as of February 16, 1996. The revisions to § 558.128 (21 CFR 558.128) list the NAS/NRC and FDA- approved conditions of use for CTC-containing Type A medicated articles.

Products which comply with the NAS/NRC findings and FDA's conclusions regarding those findings are eligible for copying under the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) (see the eighth in a series of policy letters issued to facilitate implementation of GADPTRA that published in the Federal Register of August 21, 1991 (56 FR 41561). Accordingly, sponsors may now...
obtain approval of abbreviated new animal drug applications (ANADA's) for these CTC Type A medicated articles. FDA has incorporated within § 558.128 a warning against use of CTC feed in veal calves as part of a general effort to distinguish between ruminating calves and preruminating calves based on information indicating that withdrawal periods established in ruminating calves may not be adequate for preruminating calves.

Also, the agency has removed in § 558.128 the use of the fixed combination for chlortetracycline and sulfamethazine to treat beef cattle. FDA has recodified this approval in a separate section (§ 558.140 (21 CFR 558.140)), as has been done for other fixed combinations. In addition, the agency is using this occasion, of the DESI finalization of the CTC Type A medicated articles, to amend those portions of the regulations containing CTC combination feeds (see list in § 558.128(c)(5)) to revise the CTC claim language to make it consistent with the NAS/NRCA and FDA-approved conditions of use.

Furthermore, the agency is deleting the citations for CTC in § 510.515 (21 CFR 510.515). Section 510.515 defines antibiotic drugs permitted in feed that were exempt from the requirement of certification. GADPTRA (Pub. L. 100-670) signed on November 16, 1988, removed the requirement for certification of antibiotic drugs for animal use. In fact, in a final rule published in the Federal Register of May 26, 1989 (54 FR 22741), the agency revoked the antibiotic procedural regulations. The published exemption constituted a sanction by the agency for use of the listed antibiotics. With the finalization of the DESI evaluation of the CTC products, the sanction is obsolete. Also, by deleting the CTC listing from § 510.515, the agency is correcting an error introduced when the regulation was published. Our records indicate that concurrent cites to oxytetracycline in § 510.515(b)(7)(i) and (b)(17)(ii) were incorrect, as oxytetracycline was not considered a certifiable antibiotic animal drug; therefore, it was incorrectly listed in § 510.515.

In the Federal Register of October 21, 1977 (42 FR 56264), the then Bureau of Veterinary Medicine issued a notice of opportunity for a hearing (NOOH) on a proposal to withdraw approval of certain NADA’s listed in § 558.15, for most subtherapeutic uses of tetracycline (CTC and oxytetracycline) in animal feed. The NOOH was issued in response to scientific research suggesting that subtherapeutic use of such drugs has contributed to the pool of antibiotic-resistant pathogenic microorganisms in feed animals. Furthermore, research indicated that the drug resistance could be transferred to pathogenic organisms in humans. The NOOH is still pending and approval of some of these supplements to finalize the DESI review process for CTC Type A medicated articles does not constitute a bar to subsequent action to withdraw approval on the grounds cited in the outstanding NOOH.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, 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)), these approvals for food-producing animals do not qualify for marketing exclusivity because the supplemental applications do not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approvals and conducted or sponsored by the applicant. The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency’s finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects
21 CFR Part 510
Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:


§ 510.515 [Amended]

2. Section 510.515 Animal feeds bearing or containing new animal drugs subject to the provision of section 512(n) of the act is amended in paragraph (b) by removing and reserving paragraphs (b)(7), (b)(17), (b)(25), and (b)(29); by redesignating paragraphs (b)(10) and (b)(13) as paragraphs (b)(1) and (b)(2); and in the table in paragraph (c) by removing entries 6, 7, and 8 for “Chlortetracycline.”

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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


4. Section 558.55 is amended in the table in paragraph (d)(2) under entries (i), (ii), and (iv) by revising the items for “Chlortetracycline 100 to 200” and by adding new items for “Chlortetracycline 200 to 400” to read as follows:

§ 558.55 Amprolium.
* * * * * *
(d) * * * *
(2) * * *
<table>
<thead>
<tr>
<th>combination in grams per ton</th>
<th>indications for use</th>
<th>limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlortetracycline 100 to 200</td>
<td>Chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.</td>
</tr>
<tr>
<td>Chlortetracycline 200 to 400</td>
<td>Chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by M. gallisepticum and E. coli susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.</td>
</tr>
<tr>
<td>Chlortetracycline 100 to 200</td>
<td>Chickens; prevention of coccidiosis caused by E. tenella only; control of infectious synovitis caused by M. synoviae susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.</td>
</tr>
<tr>
<td>Chlortetracycline 200 to 400</td>
<td>Chickens; prevention of coccidiosis caused by E. tenella only; control of chronic respiratory disease (CRD) and air sac infection caused by M. gallisepticum and E. coli susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.</td>
</tr>
<tr>
<td>Chlortetracycline 100 to 200</td>
<td>Chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by M. synoviae susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.</td>
</tr>
<tr>
<td>Chlortetracycline 200 to 400</td>
<td>Chickens where immunity to coccidiosis is not desired; control of chronic respiratory disease (CRD) and air sac infection caused by M. gallisepticum and E. coli susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.</td>
</tr>
</tbody>
</table>

5. Section 558.58 is amended in the table in paragraph (d)(1) by revising entry (iv) for the items “Chlortetracycline 100 to 200” and “Chlortetracycline 200” to read as follows:

§ 558.58 Amprolium and ethopabate.

(a) * * * * *

(d) * * *

(1) * * *
### Chlortetracycline 100 to 200.

For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

Do not feed to chickens producing eggs for human consumption.

Feed for 7 to 14 d.

### Chlortetracycline 200 to 400.

For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.

In low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 d; do not feed to chickens producing eggs for human consumption.

---

6. Section 558.128 is amended by revising paragraphs (a), (b), and (c)(1); by removing paragraphs (c)(2) and (c)(3); and by redesigning paragraphs (c)(4) and (c)(5) as paragraphs (c)(2) and (c)(3), to read as follows:

#### § 558.128 Chlortetracycline.

(a) Approvals. Type A medicated articles containing the following concentrations of either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride or, for products intended for use in milk replacer, chlortetracycline hydrochloride:

- (1) 50 to 100 grams per pound to 046573.
- (2) 50 to 100 grams per pound to 000004 in § 510.600(c) of this chapter.
- (3) 50 to 100 grams per pound to 000069.
- (4) 50 grams per pound to 012286.
- (5) 50 to 100 grams per pound to 053389.

(b) Related tolerances. See § 556.150 of this chapter.

(c)(1) It is used in feeds as follows:

### Chlortetracycline amount

<table>
<thead>
<tr>
<th>Amount</th>
<th>Combination</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 10 to 50 g/ton</td>
<td></td>
<td>1. Chickens; increased rate of weight gain and improved feed efficiency.</td>
<td>Do not feed to chickens producing eggs for human consumption.</td>
<td>000004, 0000069, 012286, 046573, 053389</td>
</tr>
<tr>
<td>(ii) 20 to 50 g/ton</td>
<td></td>
<td>2. Growing turkeys; increased rate of weight gain and improved feed efficiency.</td>
<td>Do not feed to turkeys producing eggs for human consumption.</td>
<td>do</td>
</tr>
<tr>
<td>(iii) 50 to 100 g/ton</td>
<td></td>
<td>3. Growing swine; increased rate of weight gain and improved feed efficiency.</td>
<td></td>
<td>do</td>
</tr>
<tr>
<td>(iv) 100 to 200 g/ton</td>
<td></td>
<td>Growing sheep; increased rate of weight gain and improved feed efficiency.</td>
<td></td>
<td>000004, 0000069, 046573, 053389</td>
</tr>
<tr>
<td>(v) 150 to 200 g/ton</td>
<td></td>
<td>Swine; reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by <em>E. Streptococci</em> susceptible to chlortetracycline.</td>
<td></td>
<td>do</td>
</tr>
<tr>
<td>(vi) 200 to 250 g/ton</td>
<td></td>
<td>Chickens; control of infectious synovitis caused by <em>Mycoplasma synoviae</em> susceptible to chlortetracycline.</td>
<td>Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.</td>
<td>do</td>
</tr>
<tr>
<td>Chlortetracycline amount</td>
<td>Combination</td>
<td>Indications for use</td>
<td>Limitations</td>
<td>Sponsor</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------</td>
<td>---------------------</td>
<td>-------------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>(v) 200 g/ton</strong></td>
<td>Turkeys; control of infectious synovitis caused by <em>M. synoviae</em> susceptible to chlortetracycline.</td>
<td>Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.</td>
<td>do</td>
<td></td>
</tr>
<tr>
<td><strong>(vi) 200 to 400 g/ton</strong></td>
<td>1. Chickens; control of chronic respiratory disease (CRD) and air sac infection caused by <em>M. gallisepticum</em> and <em>E. coli</em> susceptible to chlortetracycline.</td>
<td>Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.</td>
<td>do</td>
<td>000004</td>
</tr>
<tr>
<td></td>
<td>2. Ducks; control and treatment of fowl cholera caused by Pasteurella multocida susceptible to chlortetracycline.</td>
<td>Feed in complete ration to provide from 8 to 28 milligrams per pound of body weight per day depending upon age and severity of disease, for not more than 21 d.</td>
<td>do</td>
<td>000004, 000069, 012286, 046573, 053389</td>
</tr>
<tr>
<td><strong>(vii) 400 g/ton</strong></td>
<td>1. Turkeys; control of hexamitiasis caused by Hexamita meleagridis susceptible to chlortetracycline.</td>
<td>Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.</td>
<td>do</td>
<td>000004, 000069, 012286, 046573, 053389</td>
</tr>
<tr>
<td></td>
<td>2. Turkey poult not over 4 weeks of age; reduction of mortality due to paratyphoid caused by Salmonella typhimurium susceptible to chlortetracycline.</td>
<td>Feed continuously for not more than 14 d.</td>
<td>do</td>
<td></td>
</tr>
<tr>
<td><strong>(viii) 500 g/ton</strong></td>
<td>Chickens; reduction of mortality due to <em>E. coli</em> infections susceptible to chlortetracycline.</td>
<td>Feed for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 h prior to slaughter.</td>
<td>do</td>
<td>000004</td>
</tr>
<tr>
<td><strong>(ix) 10 mg/g of finished feed daily.</strong></td>
<td>Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by Chlamydia psittaci sensitive to chlortetracycline.</td>
<td>Feed continuously for 45 d; each bird should consume daily an amount of medicated feed equal to one fifth of its body weight. 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.”</td>
<td>000004, 000069, 012286, 046573, 053389</td>
<td></td>
</tr>
<tr>
<td><strong>(x) 0.1 mg/lb of body weight daily.</strong></td>
<td>Calves (up to 250 lb); for increased rate of weight gain and improved feed efficiency.</td>
<td>In milk replacers or starter feed; include on labeling the warning: “A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.”</td>
<td>000004, 000069, 012286, 046573, 053389</td>
<td></td>
</tr>
<tr>
<td><strong>(xi) 0.5 mg/lb of body weight daily.</strong></td>
<td>Beef cattle (over 700 lb); control of active infection of anaplasmosis caused by Anaplasma marginale susceptible to chlortetracycline.</td>
<td>Withdraw 48 h prior to slaughter.</td>
<td>do</td>
<td></td>
</tr>
<tr>
<td><strong>(xii) 10 mg/lb of body weight</strong></td>
<td>1. Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <em>E. coli</em> and bacterial pneumonia caused by <em>P. multocida</em> organisms susceptible to chlortetracycline.</td>
<td>Treat for not more than 5 d; in feed excluding milk replacers; withdraw 10 d prior to slaughter except for 24 h for sponsor 046573; include on labeling the warning: “A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.”</td>
<td>do</td>
<td></td>
</tr>
<tr>
<td>Chlortetracycline amount</td>
<td>Combination</td>
<td>Indications for use</td>
<td>Limitations</td>
<td>Sponsor</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------</td>
<td>---------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Calves (up to 250 lb); treatment of bacterial enteritis caused by <em>E. coli</em> susceptible to chlortetracycline.</td>
<td>In milk replacers or starter feed; include on labeling the warning: “A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.”</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Swine; treatment of bacterial enteritis caused by <em>E. coli</em> and <em>S. cholaearaeus</em> and bacterial pneumonia caused by <em>P. multocida</em> susceptible to chlortetracycline.</td>
<td>Feed for not more than 14 d; withdraw 5 d prior to slaughter for sponsor 012286.</td>
<td>000004, 000069, 012286, 046573, 053389</td>
</tr>
<tr>
<td>(xii) 25 mg/lb of body weight</td>
<td></td>
<td>Turkeys; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline.</td>
<td>Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.</td>
<td>do</td>
</tr>
<tr>
<td>(xiv) 25 to 70 mg/head/day</td>
<td></td>
<td>Calves (250 to 400 lb); increased rate of weight gain and improved feed efficiency.</td>
<td>Include on labeling the warning: “A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.”</td>
<td>000004, 000069, 012286, 046573, 053389</td>
</tr>
<tr>
<td>(xv) 70 mg/head/day</td>
<td></td>
<td>Growing cattle (over 400 lb) increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.</td>
<td>do</td>
<td>do</td>
</tr>
<tr>
<td>(xvi) 80 mg/head/day</td>
<td></td>
<td>Breeding sheep; reducing the incidence of (vibrionic) abortion caused by <em>Campylobacter fetus</em> infection susceptible to chlortetracycline.</td>
<td>do</td>
<td>do</td>
</tr>
<tr>
<td>(xvii) 350 mg/head/day</td>
<td></td>
<td>1. Cattle (under 700 lb); control of bacterial pneumonia associated with shipping fever complex caused by <em>Pasteurella</em> spp. susceptible to chlortetracycline.</td>
<td>Withdraw 48 h prior to slaughter.</td>
<td>000004, 000069, 012286, 046573, 053389</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Beef cattle (under 700 lb); control of active infection of anaplasmosis caused by <em>A. marginale</em> susceptible to chlortetracycline.</td>
<td>do</td>
<td>do</td>
</tr>
</tbody>
</table>

* * * * *

7. New § 558.140 is added to subpart B to read as follows:

§ 558.140 Chlortetracycline and sulfamethazine.

(a) Approvals. Type A medicated articles: 35 grams of chlortetracycline per pound with 7.7 percent (35 grams) of sulfamethazine to 000004 in § 510.600(c) of this chapter.

(b) Related tolerances. See §§ 556.150 and 556.670 of this chapter.

(c) It is used in feed for beef cattle as follows:

(1) Amount per head per day.

Chlortetracycline, 350 milligrams plus sulfamethazine, 350 milligrams.

(2) Indications for use. Aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

(3) Limitations. Feed for 28 days; withdraw 7 days prior to slaughter.

8. Section 558.175 is amended by revising paragraph (c)(2)(ii) to read as follows:

§ 558.175 Clopidol.

* * * * *

(ii) Amount per ton. Clopidol, 113.5 grams (0.0125 percent) plus chlortetracycline 100 to 200 grams.

(a) Indications for use. Aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*;

control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

(b) Limitations. Feed continuously as sole ration from the time chicks are placed in floor pens for 7 to 14 days.

* * * * *

9. Section 558.195 is amended in the table in paragraph (d) in the entry for “27.2 (0.003pct)” by removing the item for “Chlortetracycline 200” and adding in its place an item for “Chlortetracycline 100 to 200” and an item for “Chlortetracycline 200 and 400” to read as follow:

§ 558.195 Decoquinate.

* * * * *

(d) * * *
Decoquinate in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor
--- | --- | --- | --- | ---
27.2 (0.003pct) | * | * | * | *

Chlortetracycline 100 to 200. | * | * | * | 011526

Chlortetracycline 200 to 400. | * | * | Do not feed to chickens producing eggs for human consumption; feed containing 0.8 pt. of calcium for 7 to 14 days. | 011526

Chlortetracycline 100 to 200. | Chickens; control of infection of large roundworms (Ascaris galli), cecal worms (Heterakis gallinae), and capillary worms (Capillaria obsignata); control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline. | * | * | *

Chlortetracycline 200 to 400. | Chickens; control of infection of large roundworms (Ascaris galli), cecal worms (H. Gallinae), and capillary worms (Capillaria obsignata); control of chronic respiratory disease (CRD) and air sac infection caused by Mycoplasma gallisepticum and Escherichia coli susceptible to chlortetracycline. | * | * | *  

10. Section 558.274 is amended in the table in paragraph (c)(1) under entry (i) by revising the item for “Chlortetracycline 100 to 200” and adding a new item for “Chlortetracycline 200 to 400”; and under entry (ii) by removing the item for “Chlortetracycline 100 to 200” and adding in its place an item for “Chlortetracycline 400” to read as follows: § 558.274 Hygromycin B.

Hygromycin B in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor
--- | --- | --- | --- | ---
(i) | * | * | * | *

Chlortetracycline 100 to 200. | Chickens; control of infestation of large roundworms (Ascaris galli), cecal worms (Heterakis gallinae), and capillary worms (Capillaria obsignata); control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline. | * | * | *

Chlortetracycline 200 to 400. | Chickens; control of infestation of large roundworms (Ascaris galli), cecal worms (H. Gallinae), and capillary worms (Capillaria obsignata); control of chronic respiratory disease (CRD) and air sac infection caused by Mycoplasma gallisepticum and Escherichia coli susceptible to chlortetracycline. | * | * | *

(ii) | * | * | * | *

Chlortetracycline 100 to 200. | * | * | Do not feed to chickens producing eggs for human consumption; feed for 7 to 14 days; withdraw 3 days before slaughter. | *  

Chlortetracycline 200 to 400. | * | * | * | *
Hygromycin B in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor
--- | --- | --- | --- | ---
* * * * * | Chlortetracycline 400. | Swine; control of infestation of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*) and whipworms (*Trichuris suis*); treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline. | Withdraw 15 d before slaughter. | * *

12. Section 558.530 is amended by revising paragraph (a); by redesigning paragraphs (d)(2)(i)(B) and (d)(4) as paragraphs (d)(4), (d)(5), and (d)(6); by adding new paragraphs (d)(2) and (d)(3); and by revising newly redesignated paragraph (d)(4) to read as set forth below, and in newly redesignated paragraph (d)(6) by redesigning paragraphs (d)(6)(i)(a) through (d) as paragraphs (d)(6)(i)(A) through (D):
M. synoviae susceptible to chlortetracycline.

(B) Limitations. See paragraph (d)(3)(i)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(iii) Grams per ton. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 400.

(A) Indications for use. For increased rate of weight gain, improved feed efficiency; and improved pigmentation; rate of weight gain, improved feed efficiency.  

(B) Limitations. Withdraw 5 days before slaughter; as sole source of organic arsenic; feed continuously throughout growing season.

(ii) Grams per ton. Roxarsone 22.7 to 34.1 (0.0025 to 0.00375 percent) plus chlortetracycline, 400 (to administer 10 milligrams per pound of body weight).

(A) Indications for use. For increased rate of weight gain and improved feed efficiency; treatment of swine dysentery; increased rate of weight gain and improved feed efficiency.

(B) Limitations. Withdraw 5 days before slaughter; as sole source of organic arsenic; feed not more than 14 days.

(iii) Grams per ton. Roxarsone 181.5 (0.02 percent).

(A) Indications for use. For the treatment of swine dysentery.

(B) Limitations. Feed not for more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source or organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.

(iv) Grams per ton. Roxarsone, 181.5 (0.02 percent) plus chlortetracycline, 10 to 50.

(A) Indications for use. For the treatment of swine dysentery; increased rate of weight gain and improved feed efficiency.

(B) Limitations. See paragraph (d)(4)(iii)(B) of this section.

(v) Grams per ton. Roxarsone, 181.5 (0.02 percent) plus chlortetracycline, 400.

(A) Indications for use. For the treatment of swine dysentery; treatment of bacterial enteritis caused by E. coli and S. choleraesuis and bacterial pneumonia caused by P. multocida susceptible to chlortetracycline.

(B) Limitations. See paragraph (d)(4)(iii)(B) of this section.

13. Section 558.680 is amended in the table in paragraph (c)(1) under entries (i) and (ii) by revising the item for "Chlortetracycline 100 to 200"; by removing the item for "Chlortetracycline 200" and adding in its place an item for "Chlortetracycline 200 to 400" to read as follows:

§ 558.680  Zoalene.  

* * * * *

(c) * * *

(1) * * *

<table>
<thead>
<tr>
<th>Zoalene in grams/ton</th>
<th>Combination in grams/ton</th>
<th>Indications for use</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) * * *</td>
<td>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*</td>
<td>Chlortetracycline 100 to 200.</td>
<td>Replacement chickens: development of active immunity to coccidiosis; control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).</td>
</tr>
<tr>
<td></td>
<td>Chlortetracycline 200 to 400.</td>
<td>Replacement chickens: development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by M. gallisepticum and Escherichia coli susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).</td>
</tr>
<tr>
<td>(ii) * * *</td>
<td>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*</td>
<td>Chlortetracycline 100 to 200</td>
<td>Broiler chickens: prevention and control of coccidiosis; control of infectious synovitis caused by M. synoviae susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 days.</td>
</tr>
</tbody>
</table>
invited to submit comments on the interim rule provided for the public comment period to expire on July 1, 1996. Because of the significant public interest in this rule, HUD is extending the public comment period to September 15, 1996.

Dated: June 28, 1996.

Michael B. Janis,
General Deputy, Assistant Secretary for Public and Indian Housing.

EFFECTIVE DATE: March 4, 1996.

For further information contact:
Captain R. R. Pixa, JAGC, U.S. Navy; Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332-2400, Telephone number: (703) 325-9744.

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS). The Deputy Assistant Judge Advocate General (Admiralty) of the Navy has determined that a prior certification of noncompliance for USS SEAWOLF (SSN 21) should be amended. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: March 4, 1996.

For further information contact:
Captain R. R. Pixa, JAGC, U.S. Navy; Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332-2400, Telephone number: (703) 325-9744.