

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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New Animal Drugs for Use in Animal Feeds; Roxarsone; Semduramicin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is correcting the single-ingredient roxarsone Type A medicated article that may be used to formulate three-way, combination drug Type C medicated broiler chicken feeds containing semduramicin, virginiamycin, and roxarsone under a new animal drug application (NADA) recently approved for Phibro Animal Health. FDA is also amending the animal drug regulations to reflect two roxarsone Type A medicated articles approved under separate new animal drug applications (NADAs) for different conditions of use. This action is being taken to improve the accuracy of the agency's regulations.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

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SUPPLEMENTARY INFORMATION: FDA has found that the list of approved, single-ingredient Type A medicated articles used to formulate three-way, combination drug Type C medicated broiler chicken feeds containing semduramicin, virginiamycin, and roxarsone under NADA 141-226 is in error. The **Federal Register** document that described approval of that application for Phibro

Animal Health on February 23, 2004 (69 FR 13221, March 22, 2004), listed 3-NITRO (roxarsone) Type A Medicated article as the source of roxarsone; however, the correct source for this combination feed is ROXARSONE (roxarsone) Type A Medicated article, approved under NADA 92-953. At this time, FDA is amending the regulations in 21 CFR 558.555 to reflect the roxarsone Type A medicated article approved for this combination and a current tabular format.

In addition, FDA has found that the April 1, 2004, edition of parts 500 to 599 (21 CFR parts 500 to 599) of Title 21 of the Code of Federal Regulations (CFR) does not accurately reflect the approved conditions of use for roxarsone Type A medicated articles. Roxarsone is approved as single-ingredient Type A medicated articles under two separate applications, NADA 7-891 for 3-NITRO and NADA 92-953 for ROXARSONE, held by Alpharma, Inc. In error, portions of the regulation describing approvals had been consolidated in July 2000 (65 FR 45711, July 25, 2000). At this time, FDA is amending the regulations in § 558.530 to reflect two separate approvals for roxarsone Type A medicated articles with different approved conditions of use and a current tabular format.

Also, FDA has found that the approved conditions of use codified for NADA 92-953 prior to the July 2000 change were in error. A specific technical amendment to remove turkeys as an approved species (49 FR 30927, August 2, 1984) was reversed in a subsequent change that implemented revised terminology for feed premixes (51 FR 7400, March 3, 1986). At this time, FDA is amending the regulations in § 558.530 to reflect approval of NADA 92-953 for chickens only.

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 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 558.530 is amended by revising paragraphs (a) through (d)(3); removing paragraph (d)(4); and by redesignating paragraph (d)(5) as paragraph (d)(4) to read as follows:

§ 558.530 Roxarsone.

(a) *Specifications.* Type A medicated articles containing 10, 20, 50, or 80 percent roxarsone.

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

(1) No. 046573 for use of 10, 20, and 50 percent Type A medicated articles as in paragraph (d)(1)(i) of this section.

(2) No. 046573 for use of 10, 20, 50, and 80 percent Type A medicated articles as in paragraphs (d)(1) through (d)(3) of this section.

(c) *Related tolerances.* See § 556.60 of this chapter.

(d) *Conditions of use*—(1) *Chickens.* It is used in chicken feed as follows:

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) 22.7 to 45.4		Growing chickens: For increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously throughout growing period; do not feed to chickens producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness.	046573
(ii) 22.7 to 45.4	Chlortetracycline 10 to 50	Growing chickens: As in paragraph (d)(1)(i) of this section.	As in paragraph (d)(1)(i) of this section. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	
(iii) 22.7 to 45.4	Chlortetracycline 100 to 200	Growing chickens: As in paragraph (d)(1)(i) of this section; and for control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	As in paragraph (d)(1)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	
(iv) 22.7 to 45.4	Chlortetracycline 200 to 400	Growing chickens: As in paragraph (d)(1)(i) of this section; and for control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlortetracycline.	As in paragraph (d)(1)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	
(v) 22.7 to 45.4	Chlortetracycline 500	Growing chickens: As in paragraph (d)(1)(i) of this section; and for reduction of mortality due to <i>E. coli</i> infections susceptible to chlortetracycline.	As in paragraph (d)(1)(i) of this section except feed continuously for 5 days. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	

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

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) 22.7 to 45.4		Growing turkeys: For increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously throughout growing period; do not feed to turkeys producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness.	046573
(ii) 22.7 to 45.4	Chlortetracycline 10 to 50	Growing turkeys: As in paragraph (d)(2)(i) of this section.	As in paragraph (d)(2)(i) of this section. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	
(iii) 22.7 to 45.4	Chlortetracycline 200	Growing turkeys: As in paragraph (d)(2)(i) of this section; and for control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	As in paragraph (d)(2)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	
(iv) 22.7 to 45.4	Chlortetracycline 400	1. Growing turkeys: As in paragraph (d)(2)(i) of this section; and for control of hexamitiasis caused by <i>Hexamita meleagrides</i> susceptible to chlortetracycline. 2. Turkey poults not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.	As in paragraph (d)(2)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	
(v) 22.7 to 45.4	Chlortetracycline 25 mg/lb body weight daily	Growing turkeys: As in paragraph (d)(2)(i) of this section; and for control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.	As in paragraph (d)(2)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	

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

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) 22.7 to 34.1		Growing and finishing swine: For increased rate of weight gain and improved feed efficiency.	Feed continuously throughout growing period; withdraw 5 days before slaughter; as sole source of organic arsenic.	046573

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(ii) 22.7 to 34.1	Chlortetracycline 400 (to administer 10 mg/lb body weight)	Growing and finishing swine: As in paragraph (d)(3)(i) of this section; and for treatment of bacterial enteritis caused by <i>E. coli</i> and <i>S. choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.	Feed for not more than 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic.	
(iii) 181.5		Growing and finishing swine: For the treatment of swine dysentery.	Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian, withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.	046573
(iv) 181.5	Chlortetracycline 10 to 50	Growing and finishing swine: As in paragraph (d)(3)(i) of this section; and for treatment of swine dysentery.	Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.	
(v) 181.5	Chlortetracycline 400 (to administer 10 mg/lb body weight)	Growing and finishing swine: As in paragraph (d)(3)(iii) of this section; and for treatment of bacterial enteritis caused by <i>E. coli</i> and <i>S. choleraesuis</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to chlortetracycline.	Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.	

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■ 3. Section 558.555 is ^{amended by revising} revised in paragraph (d) to read as follows:

§ 558.555 Semduramicin.

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(d) Conditions of use in chickens. It is used in chicken feed as follows:

Semduramicin in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(1) 22.7 (25 ppm)		Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria acervulina</i> , <i>E. brunetti</i> , <i>E. maxima</i> , <i>E. mitis</i> , <i>E. necatrix</i> , and <i>E. tenella</i> .	Do not feed to laying hens.	066104
(2) 22.7	Bacitracin methylene disalicylate 10 to 50	Broiler chickens: As in paragraph (d)(1) of this section; for improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying hens. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.	066104
(3) 22.7	Bacitracin methylene disalicylate 10 to 50 plus roxarsone 45.4	Broiler chickens: As in paragraph (d)(4) of this section; for improved feed efficiency.	Feed continuously as sole ration. Use feed within 2 weeks of production. Do not feed to laying hens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. Withdraw 5 days before slaughter. Bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.	066104

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Semduramicin in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(4) 22.7	Roxarsone 45.4	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria acervulina</i> , <i>E. brunetti</i> , <i>E. maxima</i> , <i>E. mivati</i> , <i>E. mitis</i> , <i>E. necatrix</i> , and <i>E. tenella</i> , including some field strains of <i>E. tenella</i> that are more susceptible to semduramicin combined with roxarsone than semduramicin alone.	Feed continuously as sole ration. For broiler chickens only. Do not feed to laying hens. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.	066104
(5) 22.7	Virginiamycin 5	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying hens. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(6) 22.7	Virginiamycin 5 to 15	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain.	Feed continuously as sole ration. Do not feed to laying hens. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(7) 22.7	Virginiamycin 20	Broiler chickens: As in paragraph (d)(1) of this section; for prevention of necrotic enteritis caused by <i>Clostridium perfringens</i> susceptible to virginiamycin.	Feed continuously as sole ration. Do not feed to laying hens. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(8) 22.7	Virginiamycin 20 plus roxarsone 22.7 to 45.4	Broiler chickens: As in paragraph (d)(1) of this section; for prevention of necrotic enteritis caused by <i>Clostridium perfringens</i> susceptible to virginiamycin; for increased rate of weight gain and improved feed efficiency; and for improved pigmentation.	Feed continuously as sole ration throughout growing period. Do not feed to laying hens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdose or lack of water may result in leg weakness. Roxarsone as in § 558.530(b)(1) of this chapter provided by No. 046573 in § 510.600(c) of this chapter; semduramicin and virginiamycin as provided by No. 066104.	066104

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