

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522, 524, and 558

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

DMB

Display Date	9-6-01
Publication Date	9-7-01
Certifier	<i>Adedeo</i>

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 56 approved new animal drug applications (NADAs) and 3 approved abbreviated new animal drug applications (ANADAs) from Roche Vitamins, Inc., to Alpharma, Inc.

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

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054-1298, has informed FDA that it has transferred ownership of, and all rights and interest in, the following approved NADAs and ANADAs to Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024:

NADA No.	Product Name
33-950	Sulfamerazine in Fish Grade
35-688	Aureo SP-250; Aureomix 500
35-805	Aureomix-S 700 Crumbles; Aureomix-S 700
36-361	Amprolium Plus Ethopabate/CTC® Sodium Sulfate
40-209	Rofenaïd® 40
41-647	Aureomix-S 700-A
41-648	Aureomix-S 700-D
41-649	Aureomix-S 700-G
41-650	Aureomix-S 700-E
41-651	Aureomix-S 700-F
41-652	Aureomix-S 700-C-2
41-653	Aureomix-S 700-B
41-654	Aureomix-S 700-H
41-984	Rofenaïd® Plus Roxarsone
46-920	Baciferin® 10, 25, 40, and 50 Type A Medicated Articles
48-486	Robenz® Type A Medicated Article
48-761	Aureomycin® Type A Medicated Article
49-287	Chlorachel-50

NADA No.	Product Name
55-040	SF Mix 66
92-507	Robenz® With Aureomycin® 500
95-546	Robenz® Plus Roxarsone
96-298	Avatec® and Bovatec® Premixes
96-933	Robenz® Plus Zn Bacitracin
97-085	Robenz® Plus Bac MD
100-901	Pfichlor 100S Milk Replacer Type A Medicated Article
102-485	Avatec®/3-Nitro®
105-758	Zinc Bacitracin and Amprol HI-E®
107-996	Avatec®/Fortracin® Premix
112-661	Avatec®/Lincomix®/3-Nitro®
112-687	Avatec®/Flavomycin®/3-Nitro®
114-794	Baciferm®/Amprol HI-E® Premix
121-553	Coban®/Aureomycin®
123-154	Coban®/3-Nitro®-10/Baciferm® Premix
125-933	Romet®-30 (Sulfamerazine)
126-052	Avatec®/Baciferm®/3-Nitro®
128-686	Bio-Cox® Type A Medicated Article
131-894	Avatec®/Fortracin®/3-Nitro® Broiler Premix
132-447	Bio-Cox® Plus Roxarsone
134-185	Bio-Cox®/3-Nitro®/Flavomycin®
134-284	Bio-Cox®/Flavomycin®
135-321	Bio-Cox®/3-Nitro®/BMD®
135-746	Bio-Cox®/BMD®
136-484	Carb-O-Sep®/Baciferm®
137-536	Bio-Cox®/3-Nitro® plus Albac®
137-537	Bio-Cox®/Lincomix®
139-075	Cygro® Type A Medicated Article
139-190	Bio-Cox®/3-Nitro®/Baciferm®
139-235	Bio-Cox®/Baciferm®
140-579	Bovatec®/Terramycin®
140-581	Bio-Cox®/3-Nitro®/Lincomix®
140-859	Aureomycin®/Bio-Cox®
140-865	Monteban®/Baciferm®
140-867	Aureomycin®/Bio-Cox®/3-Nitro®
141-025	Cattlyst® Type A Medicated Article
141-109	Avatec®/Baciferm®
141-150	Avatec®/Stafac®
200-140	Aureozol® Type A Medicated Article
200-167	Aureozol® 500 Granular
200-242	Aureomycin®-50, 70, 80, 90, 100/BMD® 25, 30, 40, 50, 60, 75

Accordingly, the agency is amending the regulations in 21 CFR 558.58, 558.76, 558.78, 558.95, 558.120, 558.128, 558.140, 558.145, 558.155, 558.195, 558.305, 558.311, 558.340, 558.355, 558.363, 558.366, 558.515, 558.550, 558.575, 558.582, and 558.600 to reflect the transfer of ownership. Section 558.95 is also being amended to remove paragraph (d)(1)(x), an entry pertaining to NADA 112-687, which is redundant with § 558.311(e)(1)(ii). Other nonsubstantive changes are being made to remove incorrect drug labeler codes.

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 Parts 522 and 524

Animal drugs.

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 522, 524, and 558 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.575 [Amended]

2. Section 522.575 *Diazepam injection* is amended in paragraph (b) by removing “000004” and by adding in its place “063238”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.520 [Amended]

4. Section 524.520 *Cuprimyxin cream* is amended in paragraph (b) by removing “000004” and by adding in its place “063238”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.58 [Amended]

6. Section 558.58 *Amprolium and ethopabate* is amended in the table in paragraph (d)(1)(iii), under the "Limitations" column in the entries for "Bacitracin 4 to 50", "Bacitracin 5 to 35 plus roxarsone 34 (0.00375%)", and "Bacitracin 10 to 50 plus roxarsone 15.4 to 45.4 (0.0017% to 0.005%)" by removing "Nos. 046573 and 063238" and by adding in its place "No. 046573"; and under the "Sponsor" column by removing "063238" and "and 063238" wherever they appear.

§ 558.76 [Amended]

7. Section 558.76 *Bacitracin methylene disalicylate* is amended in the table in paragraph (d)(1)(iv), under the "Limitations" column by removing "Nos. 000004 and 046573" and by adding in its place "No. 046573"; and under the "Sponsor" column by removing "000004 and 046573" both times it appears and adding in its place "046573".

8. Section 558.78 is amended by revising paragraph (a)(1), by removing paragraph (a)(2), and by redesignating paragraph (a)(3) as paragraph (a)(2); in the table in paragraphs (d)(1)(i) and (d)(1)(ii) under the "Sponsor" column by removing "063238"; and in paragraphs (d)(1)(v) and (d)(1)(vi) under the "Sponsor" column, and in paragraph (d)(2)(ii) by removing "063238" and by adding in its place "046573" to read as follows:

§ 558.78 Bacitracin zinc.

(a) * * *

(1) No. 046573: 10, 25, 40, and 50 grams per pound as in paragraph (d) of this section.

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§ 558.95 [Amended]

9. Section 558.95 *Bambermycins* is amended by removing and reserving paragraph (d)(1)(x); and in paragraphs (d)(1)(xi)(b), (d)(1)(xii)(b), and (d)(1)(xiv)(b) by removing "063238" and by adding in its place "046573".

§ 558.120 [Amended]

10. Section 558.120 *Carbarstone (not U.S.P.)* is amended in paragraph (d)(1)(iii)(b) by removing "Nos. 046573 and 063238" and by adding in its place "No. 046573".

11. Section 558.128 is amended by revising paragraph (a); in the table in paragraph (d)(1) and in paragraph (d)(2) by removing "00004" or "000004" wherever they occur and by adding in their place "046573"; in paragraph (d)(1)(i) in entry 1, and in paragraphs (d)(1)(iv), (d)(1)(vi), and (d)(1)(viii) under the "Sponsor" column by removing "063238" and by adding in its place "046573"; in paragraph (d)(1)(i) in entry 2, and in paragraphs (d)(1)(ii), (d)(1)(iii), (d)(1)(v), (d)(1)(vii), (d)(1)(x), and (d)(1)(xii) in entry 3, and in paragraphs (d)(1)(xiv), (d)(1)(xvi), and (d)(1)(xvii) under the "Sponsor" column by removing "063238" to read as follows:

§ 558.128 Chlortetracycline.

(a) *Approvals.* See sponsors in § 510.600(c) of this chapter for 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) Nos. 000069, 046573, and 053389: 50 to 100 grams per pound.

(2) No. 017519: 50 grams per pound.

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§ 558.140 [Amended]

12. Section 558.140 *Chlortetracycline and sulfamethazine* is amended in paragraph (a) by removing "063238" and by adding in its place "046573".

§ 558.145 [Amended]

13. Section 558.145 *Chlortetracycline, procaine penicillin, and sulfamethazine* is amended in paragraph (a)(1) by removing "and 063238", and in paragraph (a)(2) by removing "063238" and by adding in its place "046573".

§ 558.155 [Amended]

14. Section 558.155 *Chlortetracycline, sulfathiazole, penicillin* is amended in paragraph (a)(1) by removing "000004 and 000010" and adding in its place "Nos. 000010 and 046573", and in paragraph (a)(2) by removing "000004 and 000010" and by adding in its place "000010 and 046573".

§ 558.195 [Amended]

15. Section 558.195 *Decoquinat*e is amended in the table in paragraph (d) in the entry for "Roxarsone 11 to 45 (0.0012–0.005 pct.) plus Bacitracin 12 to 50" under the "Limitations" column by removing "Nos. 011716, 046573, and 063238" and by adding in its place "No. 046573".

§ 558.305 [Amended]

16. Section 558.305 *Laidlomycin propionate potassium* is amended in paragraph (a) by removing "063238" and by adding in its place "046573".

§ 558.311 [Amended]

17. Section 558.311 *Lasalocid* is amended in paragraphs (b) and (e) by removing "000004" or "063238" wherever they occur and by adding in their place "046573".

§ 558.340 [Amended]

18. Section 558.340 *Maduramicin ammonium* is amended in paragraph (a) by removing “063238” and by adding in its place “046573”.

§ 558.355 [Amended]

19. Section 558.355 *Monensin* is amended in paragraphs (b)(8), (b)(9), (f)(1)(iv)(b), and (f)(1)(v)(b) by removing “063238” and by adding in its place “046573”; in paragraphs (f)(1)(xiv)(b) and (f)(1)(xvi)(b) by removing “Nos. 046573 and 063238” and by adding in its place “No. 046573”; and in paragraph (f)(1)(xv)(b) by removing “Nos. 063238 and 046573” and by adding in its place “No. 046573”.

§ 558.363 [Amended]

20. Section 558.363 *Narasin* is amended in paragraphs (a)(7) and (d)(1)(x)(B) by removing “063238” and by adding in its place “046573”.

§ 558.366 [Amended]

21. Section 558.366 *Nicarbazin* is amended in the table in paragraph (c) in the entry for the combination of nicarbazin at 113.5 grams per ton and bacitracin zinc at 4 to 50 grams per ton by removing “063238” in the “Limitations” column and by adding in its place “046573”.

§ 558.515 [Amended]

22. Section 558.515 *Robenidine hydrochloride* is amended in paragraph (a) by removing “063238” and by adding in its place “046573”; in the table in paragraph (d) in the entry for robenidine hydrochloride at 30 grams per ton as a single ingredient by removing “063238” in the “Sponsor” column and by adding in its place “046573”; in the two entries for “Bacitracin (as bacitracin zinc)” by removing “063238” in the “Sponsor” column; and in the entry for “Chlortetracycline 500” by removing “063238” from the “Sponsor” column and by adding in its place “046573”.

§ 558.550 [Amended]

23. Section 558.550 *Salinomycin* is amended in paragraph (a)(1) by removing "063238" and by adding in its place "046573"; by removing paragraph (a)(3); in paragraph (d)(1)(xvii)(C) by removing "000004" and by adding in its place "046573"; in paragraphs (d)(1) and (d)(3) by removing "063238" wherever it occurs and by adding in its place "046573"; in paragraph (d)(1)(viii)(c) by removing "(b)(1)(iv)(c)" and by adding in its place "(d)(1)(iv)(c)"; and in paragraph (d)(1)(xi)(c) by removing "(b)(1)(x)(c)" and by adding in its place "(d)(1)(x)(c)".

§ 558.575 [Amended]

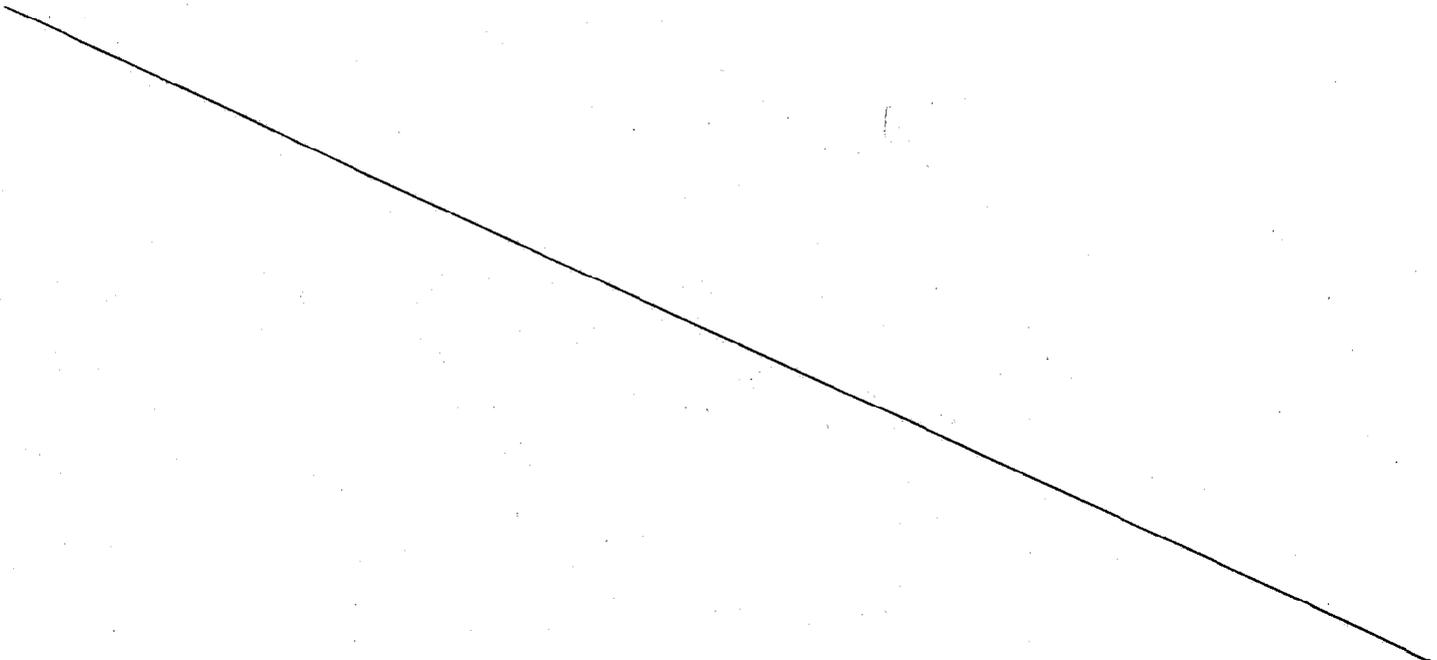
24. Section 558.575 *Sulfadimethoxine, ormetoprim* is amended in paragraphs (a)(1) and (a)(2) by removing "000004" and by adding in its place "046573".

§ 558.582 [Amended]

25. Section 558.582 *Sulfamerazine* is amended in paragraph (a) by removing "063238" and by adding in its place "046573".

§ 558.600 [Amended]

26. Section 558.600 *Tiamulin* is amended in paragraph (c)(4)(ii) by removing "046573, 053389, and 063238" and by adding in its place "046573 and 053389".



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Regina Ledesma