

| Form No.            | Edition date | Title  |
|---------------------|--------------|--|
| * * *               | * * *        | * * *  |
| I-539 Supplement A. | 03-27-01     | Filing Instructions for V nonimmigrant status. |
| * * *               | * * *        | * * *  |

14. Section 299.5 is amended in the table by adding Form "I-539 Supplement A" in proper numerical sequence, to read as follows:

**§ 299.5 Display of control numbers.**

| INS form No.       | INS form title                                  | Currently assigned OMB Control No. |
|--------------------|---|------------------------------------|
| * * *              | * * *   | * * *                              |
| I-539 Supplement A | Filing Instructions for V non-immigrant status. | 1115-0237                          |
| * * *              | * * *   | * * *                              |

Dated: August 28, 2001.

**Larry D. Thompson,**

*Acting Attorney General.*

[FR Doc. 01-22151 Filed 9-6-01; 8:45 am]

**BILLING CODE 4410-10-P**

**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.

**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 September 7, 2001.

**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 .....  | Rofenaid® 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 .....  | Rofenaid® Plus Roxarsone                              |
| 46-920 .....  | Bacifer® 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   |
| 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 ..... | Pfchlör 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 ..... | Bacifer®/Amprol HI-E® Premix                          |
| 121-553 ..... | Coban®/Aureomycin®                                    |
| 123-154 ..... | Coban®/3-Nitro®-10/Bacifer® Premix                    |
| 125-933 ..... | Romet®-30 (Sulfamerazine)                             |
| 126-052 ..... | Avatec®/Bacifer®/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®/Bacifer®                                  |
| 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®/Bacifer®                            |
| 139-235 ..... | Bio-Cox®/Bacifer®                                     |
| 140-579 ..... | Bovatec®/Terramycin®                                  |
| 140-581 ..... | Bio-Cox®/3-Nitro®/Lincomix®                           |
| 140-859 ..... | Aureomycin®/Bio-Cox®                                  |
| 140-865 ..... | Monteban®/Bacifer®                                    |

| NADA No.      | Product Name  |
|---------------|---|
| 140-867 ..... | Aureomycin®/Bio-Cox®/3-Nitro®                               |
| 141-025 ..... | Cattlyst® Type A Medicated Article                          |
| 141-109 ..... | Avatec®/Bacifer®  |
| 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.

\* \* \* \* \*

#### § 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 *Carbarsone* (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.

\* \* \* \* \*

#### § 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* 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”.

Dated: August 24, 2001.

**Claire M. Lathers,**

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

[FR Doc. 01-22470 Filed 9-6-01; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF DEFENSE****Office of the Secretary****32 CFR Part 231****RIN 0790-AG74****Procedures Governing Banks, Credit Unions and Other Financial Institutions on DoD Installations**

**AGENCY:** Department of Defense.

**ACTION:** Final rule.

**SUMMARY:** This final rule reflects the transition of operational responsibilities for banks and credit unions from the Office of the Under Secretary of Defense (Comptroller) to the Defense Finance and Accounting Service; to address changes in financial-related technology and the vehicles through which financial services are delivered (i.e., in-store banking, electronic banking (ATMs)); and incorporates the

procedural guidance contained in other DoD documents.

**DATES:** This rule is effective June 1, 2001.

**FOR FURTHER INFORMATION CONTACT:** T. Summers, 703-602-0299.

**SUPPLEMENTARY INFORMATION:****Background**

Stateside military banking began in 1941 when the Department realized that financial services were urgently needed by military and civilian personnel on domestic installations. To address this need, the Department permitted installation commanders to negotiate with nearby local banks to establish branches on their installation. Today, there are over 230 domestic installations that have either a bank or credit union or both. To ensure consistency between installations in the level, cost and types of financial services offered the Department established regulations in parts 230 and 231 to govern the operation and oversight of these institutions. These regulations limit the number of financial institutions that may operate on an installation to one bank and one credit union (with a grandfather provision). The regulations require full and open competition for a full spectrum of banking services (to include electronic banking services). Policy guidance relating to the military banking program, by regulation, is the responsibility of the Under Secretary of Defense (Comptroller) while operational guidance rests with the Defense Finance and Accounting Service (DFAS). To ensure financial services are available on our overseas installations, the Department operates the overseas military banking program. The DFAS has been assigned the program office responsibilities for this effort, which is provided under contract by a domestic financial institution. In FY 2000, the overseas military banking program contractor operated 110 banking offices and over 250 automated teller machines in 10 foreign countries. Overseas military banks support DoD personnel and their families, disbursing officers, appropriated fund activities (such as the Defense Commissary Agency) and nonappropriated fund activities (such as the Army and Air Force Exchange Service).

**Comments, and Changes to, the Proposed Rule**

The Department of Defense published a proposed rule on August 11, 1999 (64 FR 43858). Over 240 comments from 55 entities were received in response to the publication of the proposed rule. The majority of these comments focused on

three areas in the proposed rule: (1) Prohibiting the assessment of automated teller machine (ATM) surcharging; (2) the establishment of a ceiling for other fees and charges; and (3) monthly financial reporting. The first two were addressed in 32 CFR part 230. The comments and the disposition of those comments on monthly financial reporting are specifically addressed below. The remainder of the comments were either administrative in nature or suggested that additional clarification was needed in certain areas. None of these resulted in any significant changes to the proposed rule.

The previously published proposed rule (§ 231.4(g)(5)) would have required that the on-base financial institution include in its operating agreement with the installation commander a provision that it will furnish copies of its monthly financial reports and other local publications to the installation commander (or designee). Prior to the consolidation of the guidance for banks and credit unions, the provision for monthly reporting was only included in the credit union guidance with periodic financial reporting required for banks only in certain situations. Therefore, most of the comments received were objections from on-base banks. The comments reflected that the banking industry is highly regulated and quarterly reports are generated as required by Federal and State regulators. Thus, they did not see a need to require the monthly production of information that is neither requested nor needed. It was suggested that when additional information is needed, it would be more appropriate for it to be provided on an “as requested” basis. There may be occasions where the installation commander will need financial information that is unobtainable from sources other than the on-base financial institution. For example, there may be a need for financial information by the installation commander to accommodate an evaluation of a potential expansion of existing on-base financial services or information may be required to assist in the development of a solicitation when the on-base financial institution has given notice of its intent to terminate operations on the installation. Based on the comments received, the section has been revised to require an on-base financial institution furnish copies of its financial reports and other local publications only on an “as needed” basis in response to a formal request from the installation commander (or designee).