



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2014-N-0002]

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 110 approved new animal drug applications (NADAs) and 14 approved abbreviated new animal drug applications (ANADAs) for new animal drug for use in animal feed from Pfizer, Inc., including its several subsidiaries and divisions, to Zoetis, Inc.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855; 240-276-8300, [steven.vaughn@fda.hhs.gov](mailto:steven.vaughn@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 E. 42d St., New York, NY 10017, and its wholly owned subsidiaries Alpharma, LLC; Fort Dodge Animal Health, Division of Wyeth; Fort Dodge Animal Health, Division of Wyeth Holdings Corp.; and its division, Pharmacia & Upjohn Co., have informed FDA that they have transferred ownership of, and all rights and

interest in, the 110 approved NADAs and 14 approved ANADAs in Table 1 to Zoetis, Inc., 333 Portage St., Kalamazoo, MI 4900.

Table 1.--NADAs and ANADAs transferred from Pfizer, Inc., to Zoetis, Inc.

File No.	Product Name
007-616	HISTOSTAT 50 (nitarstone) Type A Medicated Article
011-116	ZOAMIX (zoalene) Type A Medicated Article
012-375	ALBAMIX (novobiocin) Type A Medicated Article
012-680	PHARMASTATIN 20 (nystatin) Type A Medicated Article
013-747	Zoalene 90 Medicated Coccidiostat
033-950	Sulfamerazine In Fish Grade
034-085	LINCOMIX (lincomycin) Type A Medicated Article
034-254	MGA (melengestrol acetate) Type A Medicated Article
035-688	AUREOMIX Granular 500 (pen G, CTC, sulfamethazine) Type A Medicated Article
035-805	AUREO S 700 Granular (CTC and sulfamethazine) Type A Medicated Article
036-361	Amprolium and ethopabate / CTC (chlortetracycline) / sodium sulfate
039-077	CSP (chlortetracycline, sulfathiazole, and penicillin G procaine) 250 and 500 Type A Medicated Articles
039-402	MGA 500 (melengestrol acetate) Liquid Type A Medicated Article
039-417	DECCOX (decoquinatate) Type A Medicated Article
040-209	ROFENAID 40 (sulfadimethoxine and ormetoprim) Type A Medicated Article
041-647	AUREOMIX S 700-A (CTC and sulfamethazine) Type A Medicated Article
041-648	AUREOMIX S 700-D (CTC and sulfamethazine) Type A Medicated Article
041-649	AUREOMIX S 700-G (CTC and sulfamethazine) Type A Medicated Article
041-650	AUREOMIX S 700-E (CTC and sulfamethazine) Type A Medicated Article
041-651	AUREOMIX S 700-F (CTC and sulfamethazine) Type A Medicated Article
041-652	AUREOMIX S 700-C-2 (CTC and sulfamethazine) Type A Medicated Article
041-653	AUREOMIX S 700-B (CTC and sulfamethazine) Type A Medicated Article
041-654	AUREOMIX S 700-H (CTC and sulfamethazine) Type A Medicated Article
044-820	AMPROL PLUS (amprolium and ethopabate) / LINCOMIX (lincomycin)
044-972	LINCOMIX (lincomycin) / COYDEN (clopidol)

045-348	ALBAC (bacitracin zinc) / DECCOX (decoquinatate)
045-444	CHLORMAX (chlortetracycline) / DECCOX (decoquinatate)
046-415	Tylosin Type A Medicated Articles
046-592	BMD (bacitracin methylene disalicylate) Type A Medicated Articles
046-666	Penicillin G Procaine Type A Medicated Articles
046-699	CHLORMAX (chlortetracycline) Type A Medicated Articles
046-718	MGA (liquid) (melengestrol acetate) / TERRAMYCIN (oxytetracycline)
046-719	MGA (dry) (melengestrol acetate) / TERRAMYCIN (oxytetracycline)
046-920	BACIFERM (bacitracin zinc) Type A Medicated Articles
047-261	DECCOX (decoquinatate) / LINCOMIX (lincomycin)
047-262	DECCOX (decoquinatate) / LINCOMIX (lincomycin)
048-486	ROBENZ (robenidone) Type A Medicated Article
048-761	AUREOMYCIN (chlortetracycline) Type A Medicated Article
048-762	Chlortetracycline Type A Medicated Article
048-763	Chlortetracycline Type A Medicated Article
048-954	ZOAMIX (zoalene) / LINCOMIX (lincomycin)
049-287	PFICHLOR (chlortetracycline) Type A Medicated Article
055-040	SF Mix 66 (chlortetracycline) Type A Medicated Article
065-020	Micro CTC (chlortetracycline) 100 Type A Medicated Article
091-668	CHLORMAX SP (chlortetracycline) 250 and 500 Type A Medicated Articles
091-749	TYLAN 40 Plus Sulfa-G
092-482	COBAN (monensin) / LINCOMIX (lincomycin)
092-507	ROBENZ / Aureomycin 500 Gm
092-522	COBAN (monensin) / LINCOMIX (lincomycin)
093-106	ROBENZ (robenidone) / LINCOMIX (lincomycin)
096-298	AVATEC and BOVATEC (lasalocid) Type A Medicated Articles
096-933	ROBENZ (robenidone) / Bacitracin Zn
097-085	Bacitracin MD / ROBENZ (robenidone)
097-505	LINCOMIX (lincomycin) Type A Medicated Articles
098-452	ALBAC 50 (bacitracin zinc) Type A Medicated Article
100-901	PFICHLOR (chlortetracycline) 100S Milk Replacer Type A Medicated Article

101-689	AVATEC (lasalocid) / LINCOMIX (lincomycin)
103-758	TERRAMYCIN (oxytetracycline) Type A Medicated Article
107-347	CHEQUE (mibolerone) Medicated Dog Food
107-996	AVATEC (lasalocid) / FORTRACIN (lasalocid)
114-794	AMPROL HI-E (amprolium and ethopabate) / BACIFERM (bacitracin zinc)
121-553	AUREOMYCIN (chlortetracycline) / COBAN (monensin)
124-309	MGA 100 and 200 (melengestrol acetate) / RUMENSIN (monensin)
125-476	MGA 500 (melengestrol acetate) / RUMENSIN (monensin)
128-686	BIO-COX (salinomycin) Type A Medicated Article
133-334	Virginiamycin Type A Medicated Article
134-284	BIO-COX (salinomycin) / FLAVOMYCIN (bambermycins)
134-830	ALBAC (bacitracin zinc) / COBAN (monensin)
135-746	BIO-COX (salinomycin) / BMD (bacitracin methylene disalicylate)
137-537	BIO-COX (salinomycin) / LINCOMIX (lincomycin)
138-456	COBAN (monensin) / BMD (bacitracin methylene disalicylate)
138-792	MGA 100 and 200 (melengestrol) / RUMENSIN (monensin) / TYLAN (tylosin)
138-870	MGA 500 (melengestrol acetate) / BOVATEC (lasalocid) / TYLAN (tylosin)
138-904	MGA (melengestrol acetate) / BOVATEC (lasalocid) / TYLAN (tylosin)
138-941	LINCOMIX (lincomycin) / BANMINTH (pyrantel)
138-992	MGA 200 (melengestrol acetate) / BOVATEC (lasalocid) / TYLAN (tylosin)
138-995	MGA (melengestrol acetate) / TYLAN (tylosin)
139-075	CYGRO (maduramicin) Type A Medicated Article
139-192	MGA 500 (melengestrol acetate) / TYLAN (tylosin)
139-235	BACIFERM (bacitracin zinc) / BIO-COX (salinomycin)
139-876	MGA 200 (melengestrol acetate) / BOVATEC (lasalocid)
140-288	MGA 500 (melengestrol acetate) / BOVATEC (lasalocid)
140-443	HYGROMIX 1.6 (hygromycin B) Premix
140-579	BOVATEC (lasalocid) / TERRAMYCIN (oxytetracycline)
140-853	BMD (bacitracin methylene disalicylate) / MONTEBAN (naracin)
140-859	AUREOMYCIN (chlortetracycline) / BIO-COX (salinomycin)
140-865	BACIFERM or ALBAC (bacitracin zinc) / MONTEBAN (naracin)

141-025	CATTLYST (laidlomycin) Type A Medicated Article
141-059	BMD (bacitracin methylene disalicylate) / CTC (chlortetracycline)
141-083	AVATEC (lasalocid) / BACIFERM (bacitracin zinc)
141-085	BMD (bacitracin methylene disalicylate) / ZOAMIX (zoalene)
141-088	HISTOSTAT (nitarosone) / BMD (bacitracin methylene disalicylate)
141-102	BMD (bacitracin methylene disalicylate) / DECCOX (decoquinatate)
141-109	AVATEC (lasalocid) / BACIFERM (bacitracin zinc)
141-124	BMD (bacitracin methylene disalicylate) / MAXIBAN (naracin and nicarbazine)
141-132	HISTOSTAT (nitarosone) / ALBAC (bacitracin zinc)
141-136	BMD (bacitracin methylene disalicylate) / BIO-COX (salinomycin)
141-140	BMD (bacitracin methylene disalicylate) / COBAN (monensin)
141-144	BMD (bacitracin methylene disalicylate) / SAFE-GUARD (fenbendazole)
141-147	DECCOX (decoquinatate) / CHLORMAX (chlortetracycline)
141-148	DECCOX (decoquinatate) / RUMENSIN (monensin)
141-149	DECCOX (decoquinatate) / RUMENSIN (monensin) / TYLAN (tylosin)
141-150	AVATEC (lasalocid) / STAFAC (virginiamycin)
141-154	BMD (bacitracin methylene disalicylate) / ROBENZ (robenidine)
141-156	BMD (bacitracin methylene disalicylate) / AMPROL (amprolium)
141-179	BMD (bacitracin methylene disalicylate) / AVATEC (lasalocid)
141-181	ALBAC (bacitracin zinc) / AVATEC (lasalocid)
141-185	DECCOX (decoquinatate) / AUREOMYCIN (chlortetracycline)
141-201	CATTLYST (laidlomycin) / AUREOMYCIN (chlortetracycline)
141-250	BOVATEC (lasalocid) / AUREOMYCIN (chlortetracycline)
200-140	AUREOZOL (pen G, CTC, sulfathiazole) Type A Medicated Article
200-167	AUREOZOL 500 Granular (pen G, CTC, sulfathiazole) Type A Medicated Article
200-204	ALBAC (bacitracin zinc) / BIO-COX (salinomycin)
200-205	ALBAC (bacitracin zinc) / AMPROL HI-E (amprolium and ethopabate)
200-210	ALBAC (bacitracin zinc) / SACOX (salinomycin)
200-212	ALBAC (bacitracin zinc) / ROBENZ
200-213	ALBAC (bacitracin zinc) / DECCOX (decoquinatate)
200-218	ALBAC (bacitracin zinc) / COYDEN 25 (clopidol)

200-223	ALBAC 50 (bacitracin zinc) Type A Medicated Article
200-242	BMD (bacitracin methylene disalicylate) / AUREOMYCIN (chlortetracycline)
200-261	CHLORMAX (chlortetracycline) / BIO-COX (salinomycin)
200-262	CHLORMAX (chlortetracycline) / SACOX (salinomycin)
200-263	CHLORMAX (chlortetracycline) / COBAN (monensin)
200-478	ALBAC 50 (bacitracin zinc) / NICARB (nicarbazin)

Accordingly, the Agency is amending the regulations in 21 CFR part 558 to reflect these transfers of ownership. In addition, the regulations are being amended to make minor corrections. This is being done to increase the accuracy and readability of the regulations.

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 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.

§ 558.76 [Amended]

2. In § 558.76, in paragraph (a), remove "046573" and in its place add "054771"; and in the table in paragraph (d)(1), in the "Limitations" column and in the "Sponsor" column, remove "046573" wherever it occurs and in its place add "054771".

§ 558.78 [Amended]

3. In § 558.78, in paragraph (b), remove "046573" and in its place add "054771"; and in the table in paragraph (d)(1), in the "Sponsor" column, remove "046573" wherever it occurs and in its place add "054771"; and in paragraph (d)(2)(ii), remove "046573" and in its place add "054771".

§ 558.128 [Amended]

4. Amend § 558.128 as follows:

a. In paragraph (b)(1), remove "046573" and in its place add "054771";

b. In the tables in paragraphs (e)(1), (e)(2), (e)(3), and (e)(5), in the "Sponsor" column, remove "046573" wherever it occurs and in its place add "054771";

c. In the table in paragraph (e)(4), in the "Limitations" column and in the "Sponsor" column, remove "046573" wherever it occurs and in its place add "054771";

d. In paragraph (e)(6)(iv), remove "per head" and in its place add "per pound of body weight"; and

e. In paragraph (e)(6)(v), remove "046573" and in its place add "054771".

§ 558.140 [Amended]

5. In § 558.140, in paragraph (a), remove "046573" and in its place add "054771"; and revise paragraph (c)(3) to read as follows:

§ 558.140 Chlortetracycline and sulfamethazine.

\* \* \* \* \*

(c) \* \* \*

(3) Limitations. Feed for 28 days, withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

§ 558.145 [Amended]

6. In § 558.145, in paragraph (a)(1), remove "046573" and in its place add "054771"; and in paragraph (a)(2) remove "046573 and 048164" and in its place add "Nos. 048164 and 054771".

§ 558.155 [Amended]

7. In § 558.155, in paragraphs (a)(1) and (2), remove "046573" and in its place add "054771".

§ 558.175 [Amended]

8. In § 558.175, in the table in paragraph (d), in the "Limitations" column and in the "Sponsor" column, remove "046573" wherever it occurs and in its place add "054771"; and in paragraph (d)(6), in the "Sponsor" column, remove "000009" and in its place add "054771".

§ 558.195 [Amended]

9. In § 558.195, in paragraph (b), remove "046573" and in its place add "054771"; in the tables in paragraphs (e)(1), (e)(2), and (e)(3), in the "Limitations" column and in the "Sponsor" column, remove "046573" wherever it occurs and in its place add "054771"; and in the table in paragraph (e)(1), in the "Limitations" column and in the "Sponsor" column, remove "000009" wherever it occurs and in its place add "054771".

§ 558.198 [Amended]

10. In § 558.198, in the tables in paragraphs (d)(1) and (2), in the "Limitations" column, remove "046573" wherever it occurs and in its place add "054771".

§ 558.258 [Amended]

11. In § 558.258, in the tables in paragraphs (e)(2)(vi) and (vii), in the "Limitations" column and in the "Sponsor" column, remove "046573" and in its place add "054771"; and in paragraphs (e)(2)(ii) through (v), in the "Limitations" column, remove "000009" and in its place add "054771".

§ 558.305 [Amended]

12. In § 558.305, in paragraph (b), remove "046573" and in its place add "054771"; and in the table in paragraph (e) in the "Sponsor" column, remove "046573" wherever it occurs and in its place add "054771".

§ 558.311 [Amended]

13. In § 558.311, in paragraphs (b)(1) through (4) and (6) and (7), remove "046573" and in its place add "054771"; in the table in paragraph (e)(1), in the "Limitations" column and in the "Sponsor" column, remove "046573" wherever it occurs and in its place add "054771", in the "Limitations" column, remove "000009" where it occurs and in its place add "054771", in the "Limitations" column, remove "000004" where it occurs and in its place add "054771"; and in paragraphs (e)(2)(v), (e)(3)(v), and (e)(4)(v), remove "046573" and in its place add "054771".

§ 558.325 [Amended]

14. In § 558.325, in paragraphs (a)(1) and (c)(3)(i), remove "000009" and in its place add "054771"; and in the tables in paragraphs (d)(1) and (2), in the "Sponsor" column, remove "000009" wherever it occurs and in its place add "054771".

§ 558.340 [Amended]

15. In § 558.340, in paragraph (a), remove "046573" and in its place add "No. 054771".

§ 558.342 [Amended]

16. In § 558.342, in paragraph (b)(1), remove "000009" and in its place add "054771"; in the table in paragraph (e)(1), in the "Limitations" column and in the "Sponsor" column, remove "000009" wherever it occurs and in its place add "054771", and in the "Limitations" column, remove "046573" wherever it occurs and in its place add "054771".

§ 558.348 [Amended]

17. In § 558.348, in paragraph (a), remove "000009" and in its place add "No. 054771".

§ 558.355 [Amended]

18. In § 558.355, in paragraphs (b)(8), (b)(9), and (b)(11), remove "046573" and in its place add "054771"; in paragraphs (f)(1)(iii)(b), (f)(1)(iv)(b), (f)(1)(v)(b), (f)(1)(vii)(b), (f)(1)(xiv)(b), (f)(1)(xxv)(b), (f)(1)(xxix)(b), (f)(1)(xxx)(b), (f)(2)(ii)(b), (f)(2)(iii)(b), (f)(4)(ii)(b), (f)(4)(iii)(b), (f)(4)(iv)(b), (f)(4)(v)(b), remove "046573" and in its place add "054771"; and revise paragraph (f)(1)(i)(b) to read as follows:

§ 558.355 Monensin.

\* \* \* \* \*

(f) \* \* \*

(1) \* \* \*

(i) \* \* \*

(b) Limitations. Feed continuously as the sole ration. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Do not feed to laying chickens.

\* \* \* \* \*

## § 558.363 [Amended]

19. In § 558.363, in paragraphs (a)(6) and (a)(7), remove "046573" and in its place add "054771"; in paragraph (d)(1)(vi)(B) and (d)(1)(x)(B), remove "046573" and in its place add "054771".

## § 558.364 [Amended]

20. In § 558.364, in paragraph (a), remove "000009" and in its place add "054771"; and in the table in paragraph (d), in the "Sponsor" column, remove "000009" wherever it occurs and in its place add "054771".

## § 558.366 [Amended]

21. In § 558.366, in the table in paragraph (d), in the "Limitations" column and in the "Sponsor" column, remove "046573" wherever it occurs and in its place add "054771" and in paragraph (d), in the "Limitations" column, remove "000009" wherever it occurs and in its place add "054771".

## § 558.369 [Amended]

22. In § 558.369, in paragraph (a), remove "046573" and in its place add "054771".

## § 558.415 [Amended]

23. In § 558.415, redesignate paragraphs (b) and (c) as paragraphs (c) and (d); revise paragraph (a); and add new paragraph (b) to read as follows:

§ 558.415 Novobiocin.

(a) Specifications. Type A medicated article containing 25 grams of novobiocin activity per pound.

(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

\* \* \* \* \*

24. In § 558.430, redesignate paragraphs (b) and (c) as paragraphs (c) and (d); revise paragraph (a); and add new paragraph (b) to read as follows:

§ 558.430 Nystatin.

(a) Specifications. Type A medicated article containing 20 grams of nystatin activity per pound.

(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

\* \* \* \* \*

§ 558.460 [Amended]

25. In § 558.460, in paragraph (b), remove "046573" and in its place add "054771"; and in the table in paragraph (d)(1)(i), in the "Sponsor" column, remove "000069, 046573" and in its place add "054771, 066104"; and in paragraphs (d)(1)(ii) and (iii), in the "Sponsor" column, remove "Do." and in its place add "054771, 066104".

§ 558.464 [Amended]

26. In § 558.464, in paragraphs (a)(1) and (2), remove "000069" and in its place add "054771".

§ 558.485 [Amended]

27. In § 558.485, in paragraph (b)(7), remove "000069 and 017135" and in its place add "017135 and 054771"; and in paragraph (e)(1)(xii)(C), remove "000009" and in its place add "054771".

§ 558.500 [Amended]

28. In § 558.500, in paragraphs (e)(2)(viii) and (x), in the "Limitations" column, remove "000009" and in its place add "054771".

§ 558.515 [Amended]

29. In § 558.515, in paragraph (a), remove "046573" and in its place add "054771"; in the table in paragraph (d), in the "Sponsor" column, remove "046573" wherever it occurs and in its place add "054771" and in the "Sponsor" column, remove "000009" where it occurs and in its place add "054771".

§ 558.550 [Amended]

30. In § 558.550, in paragraphs (b)(1), (d)(1)(iii)(c), (d)(1)(vi)(c), (d)(1)(vii)(c), (d)(1)(xvi)(c), (d)(1)(xx)(C), (d)(1)(xxi)(C), (d)(1)(xxii)(B), (d)(1)(xxiii)(b), (d)(3)(ii)(B), (d)(3)(iii)(B), (d)(3)(v)(B), (d)(4)(i)(b), remove "046573" and in its place add "054771"; and in paragraph (d)(1)(xiii)(c), remove "000009" and in its place add "054771".

§ 558.555 [Amended]

31. In § 558.555, in paragraphs (d)(2), (d)(3), (d)(4), and (d)(8), in the "Limitations" column, remove "046573" and in its place add "054771".

§ 558.575 [Amended]

32. In § 558.575, in paragraph (a)(1), remove "046573" and in its place add "054771".

§ 558.582 [Amended]

33. In § 558.582, in paragraph (a), remove "046573" and in its place add "054771".

§ 558.600 [Amended]

34. In paragraph (e)(1)(iii) of § 558.600, in the "Indications for use" column, remove "susceptible" wherever it occurs and in its place add "sensitive"; in the "Limitations" column, add "Use as only source of tiamulin."; and in the "Limitations" column, remove "046573" and in its place add "054771".

§ 558.625 [Amended]

35. In § 558.625, remove and reserve paragraphs (b)(57) and (83); in paragraph (b)(54), remove "046573" and in its place add "054771"; and add paragraph (b)(10) to read as follows:

§ 558.625 Tylosin.

\* \* \* \* \*

(b) \* \* \*

(10) To No. 012286: 0.4, 0.8, and 1.6 grams per pound, paragraph (f)(1)(vi)(a) of this section; 20, 40, and 100 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

\* \* \* \* \*

§ 558.630 [Amended]

36. In § 558.630, in paragraph (b)(5), remove "046573" and in its place add "054771".

§ 558.635 [Amended]

37. In § 558.635, in paragraph (a)(2), remove "046573" and in its place add "054771".

§ 558.680 [Amended]

38. In § 558.680, in paragraph (b), remove "046573" and in its place add "054771".

Dated: February 28, 2014.

Steven D. Vaughn,

Director,

Office of New Animal Drug Evaluation,

Center for Veterinary Medicine.