



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, and 558

[Docket No. FDA-2013-N-0002]

New Animal Drugs; Changes 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 21 approved new animal drug applications (NADAs) and 43 approved abbreviated new animal drug applications (ANADAs) from Teva Animal Health, Inc., to Bayer HealthCare LLC.

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

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Teva Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503 has informed FDA that it has transferred ownership of, and all rights and interest in, the following 21 approved NADAs and 43 approved ANADAs to Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201:

Table 1.--Applications Transferred

Application No.	Trade Name
6-391	S.Q. (sulfaquinoxaline) 40% Type A Medicated Article
6-677	S.Q. (sulfaquinoxaline) 20% Solution
7-087	Sulfaquinoxaline Solubilized
33-157	SPECTAM (spectinomycin) Scour Halt
40-040	SPECTAM (spectinomycin) Injectable Solution
45-416	TEVCODYNE (phenylbutazone) Injectable Solution
48-287	Oxytetracycline-50 Injectable Solution
55-002	TEVCOCIN (chloramphenicol) Injection
65-110	PEN-G-MAX (penicillin G procaine) Injectable Suspension
65-498	DUAL-CILLIN (penicillin G benzathine and penicillin G procaine)
91-818	Phenylbutazone Tablets, USP 1 gram
93-483	SPECTAM (spectinomycin) Injectable Solution
94-170	Phenylbutazone Tablets, USP 100 or 200 mg
99-169	Oxytocin Injection
119-142	PVL Iron Dextran Injectable (iron hydrogenated dextran injection)
123-815	Dexamethasone Sodium Phosphate Injection
124-241	PVL (oxytocin) Injectable
128-089	ZONOMETH (dexamethasone) Solution
140-270	SULFASURE (sulfamethazine) SR Cattle Bolus
141-070	RAPINOVET (propofol) Injectable Emulsion
141-245	TRIBUTAME (embutramide, chloroquine, and lidocaine) Euthanasia Solution
200-042	Ketamine Hydrochloride Injection, USP
200-068	Oxytetracycline Hydrochloride Injection 100
200-069	FERTELIN (gonadorelin diacetate tetrahydrate) Injection
200-108	Dexamethasone Solution
200-118	Neomycin Oral Solution
200-123	MAXIM-200 (oxytetracycline hydrochloride) Injection

200-124	Flunixin Meglumine Injection
200-126	Phenylbutazone 20% Injection
200-137	Gentamicin Sulfate Solution (IU)
200-147	Gentamicin Sulfate Injection
200-153	NEO 200 (neomycin sulfate) Oral Solution
200-162	Tripelennamine Hydrochloride Injection
200-174	Gentamicin Sulfate Pig Pump Oral Solution
200-177	Sulfadimethoxine Injection 40%
200-178	Amikacin Sulfate Injection
200-181	Amikacin Sulfate Solution
200-192	Sulfadimethoxine 12.5% Oral Solution
200-193	Clindamycin Hydrochloride Oral Liquid
200-202	PHOENECTIN (ivermectin) Oral Solution
200-219	Ivermectin Pour-On for Cattle
200-228	PHOENECTIN (ivermectin) Injectable Solution
200-230	Guaifenesin Injection
200-246	Pyrantel Pamoate Oral Suspension (OTC and Rx)
200-248	Pyrantel Pamoate Oral Suspension
200-253	PROSTAMATE (dinoprost tromethamine) Injectable Solution
200-254	Iron Dextran Injection - 100
200-256	Iron Dextran Injection - 200
200-265	Praziquantel Tablets (OTC and Rx)
200-286	PHOENECTIN (ivermectin) Paste 1.87%
200-287	GBC (gentamicin sulfate, betamethasone valerate, and clotrimazole) Ointment
200-293	Furosemide Injection 5%
200-297	Ivermectin Chewable Tablets
200-298	Clindamycin Hydrochloride Capsules
200-319	Acepromazine Maleate Injection
200-322	Butorphanol Tartrate Injection
200-342	Pyrantel Pamoate Paste
200-351	Lincomycin Injectable, USP
200-360	TIAGARD (tiamulin) Liquid Concentrate
200-365	ROBINUL-V (glycopyrrolate) Injectable
200-382	Furosemide Syrup 1%
200-389	Amprolium 9.6% Oral Solution

200-408	Butorphanol Tartrate Injection
200-463	Amprolium-P 9.6% Oral Solution

Accordingly, the Agency is amending the regulations in 21 CFR parts 510, 520, 522, 524, 529, and 558 to reflect these transfers of ownership. Following these changes of sponsorship, Teva Animal Health, Inc., is no longer the sponsor of an approved application. As such, 21 CFR 510.600 is being amended to remove the entries for this firm.

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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 529

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 510, 520, 522, 524, 529, 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:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. In §510.600, in the table in paragraph (c)(1), remove the entry for “Teva Animal Health, Inc.”; and in the table in paragraph (c)(2), remove the entry for “059130”.

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.100 [Amended]

4. In paragraph (b)(3) of § 520.100, remove “059130” and in its place add “000859”.

§ 520.446 [Amended]

5. In paragraph (b)(1) of § 520.446, remove “059130” and in its place add “000859”.

§ 520.447 [Amended]

6. In paragraph (b) of § 520.447, remove “000009, 051311, 058829, and 059130” and in its place add “000009, 000859, 051311, and 058829”.

§ 520.1010 [Amended]

7. In paragraph (b)(3) of § 520.1010, remove “058829 and 059130” and in its place add “000859 and 058829”.

§ 520.1044b [Amended]

8. In paragraph (b) of § 520.1044b, remove “059130” and in its place add “000859”.

§ 520.1192 [Amended]

9. In paragraph (b)(2) of § 520.1192, remove “051311, 054925, 059130, and 061623” and in its place add “000859, 051311, 054925, and 061623”.

§ 520.1193 [Amended]

10. In paragraph (b)(2) of § 520.1193, remove “051311 and 059130” and in its place add “000859 and 051311”.

§ 520.1195 [Amended]

11. In paragraph (b)(1) of § 520.1195, remove “050604, 054925, and 059130” and in its place add “000859, 050604, and 054925”.

§ 520.1484 [Amended]

12. In paragraph (b)(3) of § 520.1484, remove “000009, 054925, 058005, and 059130” and in its place add “000009, 000859, 054925, and 058005”.

§ 520.1720a [Amended]

13. In paragraph (b)(2) of § 520.1720a, remove “059130” and in its place add “000859”.

§ 520.1870 [Amended]

14. In paragraph (b)(2) of § 520.1870, remove “059130” and in its place add “000859”.

§ 520.2043 [Amended]

15. In paragraph (b)(1) of § 520.2043, remove “000069, 058829, and 059130” and in its place add “000069, 000859, and 058829”.

§ 520.2044 [Amended]

16. In paragraph (b)(2) of § 520.2044, remove “059130” and in its place add “000859”.

§ 520.2123c [Amended]

17. In paragraph (b) of § 520.2123c, remove “059130” and in its place add “000859”.

§ 520.2220a [Amended]

18. In paragraph (a)(1) of § 520.2220a, remove “000010, 000069, 054925, 057561, and 059130” and in its place add “000010, 000069, 000859, 054925, and 057561”.

§ 520.2260b [Amended]

19. In paragraph (f)(1) of § 520.2260b, remove “059130” and in its place add “000859”.

§ 520.2325a [Amended]

20. In paragraph (a)(1) of § 520.2325a, remove “059130” and in its place add “000859”.

21. In § 520.2455, revise paragraph (b)(2) and add paragraph (b)(3) to read as follows:

§ 520.2455 Tiamulin.

* * * * *

(b) * * *

(2) No. 066104 for the product described in paragraph (a)(1) of this section.

(3) No. 000859 for the product described in paragraph (a)(3) of this section.

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PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.23 [Amended]

23. In paragraph (b)(2) of § 522.23, remove “059130” and in its place add “000859”.

§ 522.56 [Amended]

24. In paragraph (b) of § 522.56, remove “059130” and in its place add “000859”.

§ 522.246 [Amended]

25. In § 522.246, in paragraphs (b)(2) and (b)(3), remove “059130” and in its place add “000859”.

§ 522.390 [Amended]

26. In paragraph (b) of § 522.390, remove “059130” and in its place add “000859”.

§ 522.540 [Amended]

27. In § 522.540, in paragraphs (a)(2)(i), (d)(2)(i), and (e)(2), remove “059130” and in its place add “000859”; in paragraphs (b)(3)(i), (b)(3)(ii), (c)(3)(i), and (c)(3)(ii), remove the footnote reference “1”; and remove the text of footnote 1.

§ 522.810 [Amended]

28. In paragraph (b) of § 522.810, remove “059130” and in its place add “000859”.

§ 522.1010 [Amended]

29. In paragraph (b)(3) of § 522.1010, remove “059130” and in its place add “000859”.

§ 522.1044 [Amended]

30. In paragraph (b)(4) of § 522.1044, remove “059130” and in its place add “000859”.

§ 522.1066 [Amended]

31. In paragraph (b) of § 522.1066, remove “059130” and in its place add “000859”.

§ 522.1086 [Amended]

32. In paragraph (b) of § 522.1086, remove “037990 and 059130” and in its place add “000859 and 037990”.

§ 522.1182 [Amended]

33. In § 522.1182, in paragraph (b)(1), remove “042552 and 059130” and in its place add “000859 and 042552”; in paragraph (b)(6), remove “058005 and 059130” and in its place add “000859 and 058005”; and in paragraph (b)(7), remove “042552 and 059130” and in its place add “000859 and 042552”.

§ 522.1192 [Amended]

34. In paragraph (b)(2) of § 522.1192, remove “055529, 058005, 059130, and 061623” and in its place add “000859 055529, 058005, and 061623”.

§ 522.1222a [Amended]

35. In paragraph (b) of § 522.1222a, remove “059130” and in its place add “000859”.

§ 522.1260 [Amended]

36. In paragraph (b)(2) of § 522.1260, remove “058005 and 059130” and in its place add “000859 and 058005”.

§ 522.1660a [Amended]

37. In paragraph (b) of § 522.1660a, remove “000010, 000069, 048164, 055529, 057561, 059130, and 061623” and in its place add “000010, 000069, 000859, 048164, 055529, 057561, and 061623”.

§ 522.1662a [Amended]

38. In paragraph (i)(2) of § 522.1662a, remove “059130” and in its place add “000859”.

§ 522.1680 [Amended]

39. In paragraph (b) of § 522.1680, remove “000010, 000856, 059130, 059130, and 061623” and in its place add “000010, 000856, 000859, and 061623”.

§ 522.1696a [Amended]

40. In paragraph (b)(2) of § 522.1696a, remove “055529, 059130, and 061623” and in its place add “000859, 055529, and 061623”.

§ 522.1696b [Amended]

41. In § 520.1696b:

a. In paragraph (b)(1), remove “053501, 055529, and 059130” and in its place add “000859, 053501, and 055529”.

b. In paragraph (d)(2)(i)(A), remove “053501, 055529, 059130, and 061623” and in its place add “000859, 053501, 055529, and 061623”.

c. In paragraph (d)(2)(iii)(B), remove “055529 and 059130” and in its place add “000859 and 055529”.

§ 522.1720 [Amended]

42. In paragraph (b)(1) of § 522.1720, remove “059130” and in its place add “000859”.

§ 522.2005 [Amended]

43. In paragraph (b)(1) of § 522.2005, remove “059130” and in its place add “000859”.

§ 522.2120 [Amended]

44. In paragraph (b) of § 522.2120, remove “059130” and in its place add “000859”.

§ 522. 2220 [Amended]

45. In paragraph (a)(2)(iii) of § 522.2220, remove “059130” and in its place add “000859”.

§ 522.2615 [Amended]

46. In paragraph (b) of § 522.2615, remove “053501 and 059130” and in its place add “000859 and 053501”.

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1044g [Amended]

48. In paragraph (b)(3) of § 524.1044g, remove “059130” and in its place add “000859”.

§ 524.1193 [Amended]

49. In paragraph (b)(2) of § 524.1193, remove “054925, 059130, and 066916” and in its place add “000859, 054925, and 066916”.

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

50. The authority citation for 21 CFR part 529 continues to read as follows:

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

§ 529.56 [Amended]

51. In paragraph (b) of § 529.56, remove “059130” and in its place add “000859”.

§ 529.1044a [Amended]

52. In paragraph (b) of § 529.1044a, remove “000010, 000061, 000856, 057561, 058005, 059130, and 061623” and in its place add “000010, 000061, 000856, 000859 057561, 058005, and 061623”.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.586 [Amended]

54. In paragraph (b) of § 558.586, remove “059130” and in its place add “000859”.

Dated: March 12, 2013.

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