

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 March 22, 2013.**FOR FURTHER INFORMATION CONTACT:** Steven D. Vaughn, Center for VeterinaryMedicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855; 240-276-8300; email: steven.vaughn@fda.hhs.gov.**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.

TABLE 1—APPLICATIONS TRANSFERRED—Continued

Application No.	Trade name
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.

Steven D. Vaughn,

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

[FR Doc. 2013-06126 Filed 3-21-13; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2013-0006]

Special Local Regulation; Southern California Annual Marine Events for the San Diego Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the 2013 San Diego Crew Classic Special Local Regulation located in the regulated area encompasses that portion of Mission Bay, San Diego, California bounded by Enchanted Cove, Fiesta Island, Pacific Passage and DeAnza Point, from 7 a.m. to 7 p.m. on April 6, 2013 and 7 a.m. to 7 p.m. on April 7, 2013. This action is necessary to provide to provide for the safety of the participants, crew, spectators, sponsor vessels of the event, and general users of the waterway. During the enforcement period, no spectators shall anchor, block, loiter in, or impede the transit of participants or official patrol vessels in the regulated area during the effective dates and times, unless cleared for such entry by Coast Guard Patrol Commander or through an official supporting vessel.

DATES: The regulations in 33 CFR 100.1101 will be enforced from 7 a.m. to 7 p.m. on April 6, 2013 and 7 a.m. to 7 p.m. on April 7, 2013.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Petty Officer Bryan Gollogly, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone 619-278-7656, email D11-PF-MarineEventsSanDiego@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Special Local Regulation for the 2013 San Diego Crew Classic in 33 CFR 100.1101 from 7 a.m. to 7 p.m. on April 6, 2013 and from 7 a.m. to 7 p.m. on April 7, 2013.

Under provisions of 33 CFR 100.1101, a vessel may not enter the regulated area, unless it receives permission from the COTP. Spectator vessels may safely transit outside the regulated area but

may not anchor, block, loiter, or impede the transit of participants or official patrol vessels. The Coast Guard may be assisted by other Federal, State, or Local law enforcement agencies in enforcing this regulation.

This notice is issued under authority of 33 CFR 100.1101 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of this enforcement period via the Local Notice to Mariners. If the Captain of the Port or his designated representative determines that the regulated area need not be enforced for the full duration stated on this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: March 6, 2013.

S.M. Mahoney,

*Captain, US Coast Guard, Captain of the Port
San Diego.*

[FR Doc. 2013-06587 Filed 3-21-13; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF EDUCATION

34 CFR Parts 600, 602, 603, 668, 682, 685, 686, 690, and 691

[Docket ID ED-2010-OPE-0004]

RIN 1840-AD02

Program Integrity Issues

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Final regulations; revisions to preamble.

SUMMARY: On October 29, 2010, the Department of Education published in the **Federal Register** final regulations for improving integrity in the programs authorized under title IV of the Higher Education Act of 1965, as amended (HEA) (October 29, 2010, final regulations). This document revises the preamble discussion to the October 29, 2010, final regulations in accordance with the remand in *Association of Private Sector Colleges and Universities v. Duncan* (D.C. Cir. 2012).

DATES: These revisions apply to the preamble for the October 29, 2010, regulations (75 FR 66832), which were generally effective July 1, 2011.

FOR FURTHER INFORMATION CONTACT: Marty Guthrie, U.S. Department of Education, 1990 K Street NW., Room 8042, Washington, DC 20006. Telephone: (202) 219-7031 or by email at Marty.Guthrie@ed.gov.

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Federal Relay Service (FRS), toll free, at 1-800-877-8339.

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SUPPLEMENTARY INFORMATION: The October 29, 2010, final regulations (75 FR 66832) amended the regulations for Institutional Eligibility Under the HEA, the Secretary's Recognition of Accrediting Agencies, the Secretary's Recognition Procedures for State Agencies, the Student Assistance General Provisions, the Federal Family Education Loan (FFEL) Program, the William D. Ford Federal Direct Loan Program, the Teacher Education Assistance for College and Higher Education (TEACH) Grant Program, the Federal Pell Grant Program, and the Academic Competitiveness Grant (ACG) and National Science and Mathematics Access to Retain Talent Grant (National Smart Grant) Programs. This document revises the preamble discussion to the October 29, 2010, final regulations in accordance with the remand in *Association of Private Sector Colleges and Universities v. Duncan*, 681 F.3d 427 (D.C. Cir. 2012).

We note that the Court in *APSCU v. Duncan*, also remanded certain provisions of the Department's misrepresentation regulations for revision consistent with the Court's opinion. We will be publishing a separate notice in the **Federal Register** addressing this issue.

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