Note. The Commission has the power under Section 19(b)(3)(C) of the Act summarily to temporarily suspend within sixty days of its filing any proposed rule change which has taken effect upon filing pursuant to Section 19(b)(3)(A) of the Act or was put into effect summarily by the Commission pursuant to Section 19(b)(3)(B) of the Act. In exercising its summary power under Section 19(b)(3)(B), the Commission is required to make one of the findings described above but may not have a full opportunity to make a determination that the proposed rule change otherwise is consistent with the requirements of the Act and the rules and regulations thereunder. The Commission will generally exercise its summary power under Section 19(b)(3)(B) on condition that the proposed rule change to be declared effective summarily shall also be subject to the filing procedures of Section 19(b)(1) of the Act, for approval pursuant to Section 19(b)(2). Accordingly, in most cases, a summary order under Section 19(b)(3)(B) shall be effective until such time as the Commission enters an order, pursuant to Section 19(b)(2)(A) of the Exchange Act, to approve such proposed rule change or, depending on the circumstances, until such time as the Commission summarily temporarily suspends the rule change pursuant to Section 19(b)(3)(C) or, alternatively, until such time as the Commission, at the conclusion of proceedings to determine whether to approve or disapprove the proposed rule change, enters an order, pursuant to Section 19(b)(2)(B), approving or disapproving such proposed rule change. Similarly, the Commission requires that any proposed rule change which has taken effect upon filing pursuant to paragraph (B)(II) of Rule 19b–4(f)(4)(ii) shall also be subject to the filing procedures of Section 19(b)(1) of the Act, for approval pursuant to Section 19(b)(2) of the Act. Accordingly, such rule change shall be effective until such time as the Commission enters an order, pursuant to Section 19(b)(2)(A) of the Exchange Act, to approve such proposed rule change or, depending on the circumstances, until such time as the Commission summarily temporarily suspends the rule change pursuant to Section 19(b)(3)(C) or, alternatively, until such time as the Commission, at the conclusion of proceedings to determine whether to approve or disapprove the proposed rule change, enters an order, pursuant to Section 19(b)(2)(B), approving or disapproving such proposed rule change.

By the Commission.

Dated: April 3, 2013.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2013–08141 Filed 4–8–13; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 526, 529, and 558

[Docket No. FDA–2013–N–0002]

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 43 approved new animal drug applications (NADAs) and 3 approved abbreviated new animal drug applications (ANADAs) from Boehringer Ingelheim Vetmedica, Inc. to Strategic Veterinary Pharmaceuticals, Inc.

DATES: This rule is effective April 9, 2013.

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, email: *steven.vaughn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002 has informed FDA that it has transferred ownership of, and all rights and interest in, the following 43 approved NADAs and 3 approved ANADAs to Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503:

TABLE 1.—APPLICATIONS TRANSFERRED

Application No.	Trade name
11–531	DIZAN (dithiazanine iodide) Tablets.
11–674	DIZAN (dithiazanine iodide) Powder.
12–469	DIZAN Suspension With Piperazine.
31–512	ATGARD (dichlovos) Swine Wormer Type A Medicated Article.
33–803	TASK (dichlovos) Dog Anthelmintic.
35–918	EQUIGARD (dichlovos).
38–200	MEDAMYCIN (oxytetracycline hydrochloride) Soluble Antibiotic.
39–483	BIO-TAL (thiamylal sodium) Injectable Solution.
40–848	ATGARD C (dichlovos) Swine Wormer Type A Medicated Article.
43–606	ATGARD V (dichlovos) Swine Wormer Type A Medicated Article.
45–143	OXYJECT (oxytetracycline hydrochloride) Injectable Solution.
47–278	OXY-TET 50 (oxytetracycline hydrochloride) Injectable Solution.
47–712	BIZOLIN-100 (phenylbutazone) Tablets.
48–010	ANAPLEX (dichlorophene and toluene) Capsules.
48–237	EQUIGEL (dichlovos) Oral Gel.
48–271	TASK (dichlovos) Tablets.
49–032	ATGARD C (dichlovos) 9.6% Type A Medicated Article.
55–097	DRY-MAST (penicillin G procaine/dihydrostreptomycin sulfate) Intramammary Infusion.
65–178	FERMYCIN (chlortetracycline hydrochloride or chlortetracycline bisulfate) Soluble Powder.
65–461	ANACETIN (chloramphenicol) Tablets.
65–481	Chlortetracycline Pneumonia/Calf Scour Boluses.
65–486	Chlortetracycline Bisulfate Soluble Powder.
65–491	MEDICHOL (chloramphenicol) Tablets.
65–496	Tetracycline Soluble Powder.
92–837	NEMACIDE (diethylcarbamazine citrate) Oral Syrup.
93–516	BIZOLIN (phenylbutazone) Injection 20%.
97–452	OXYJECT 100 (oxytetracycline hydrochloride) Injectable Solution.
98–569	MEDACIDE-SDM (sulfadimethoxine) Injection 10%.
99–618	BIZOLIN (phenylbutazone) 1–G Tablets.
108–963	MEDAMYCIN (oxytetracycline hydrochloride) Injectable Solution.

TABLE 1.—APPLICATIONS TRANSFERRED—Continued

Application No.	Trade name
109–305	Oxytocin Injection.
117–689	NEUROSYN (primidone) Tablets.
125–797	Nitrofurazone Dressing.
126–236	Nitrofurazone Soluble Powder.
126–676	D & T (dichlorophene and toluene) Worm Capsules.
127–627	NEMACIDE-C (diethylcarbamazine citrate) Tablets.
128–069	NEMACIDE (diethylcarbamazine citrate) Chewable Tablets.
132–028	ANESTATAL (thiamylal sodium) Powder for Injection.
135–771	Methylprednisolene Tablets.
136–212	Methylprednisolone Acetate Injectable Suspension.
137–310	Gentamicin Sulfate Injectable Solution.
138–869	Triamcinolone Acetonide Injectable Suspension.
140–442	Xylazine HCl Injection.
200–023	Gentamicin Sulfate Intrauterine Solution.
200–029	Ketamine Hydrochloride Injection.
200–165	SDM (sulfadimethoxine) 12.5% Oral Solution.

Accordingly, the Agency is amending the regulations in 21 CFR parts 510, 520, 522, 524, 526, 529, and 558 to reflect the transfer of ownership.

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, 526, 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, 526, 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.

■ 2. In the table in paragraph (c)(1) of § 510.600, alphabetically add an entry for ''Strategic Veterinary Pharmaceuticals, Inc.''; and in the table in paragraph (c)(2), numerically add an entry for ''054628'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503	054628
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
054628	Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503
* * * * *	

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.

§ 520.390a [Amended]

■ 4. In paragraph (b)(1)(i) of § 520.390a, remove ''000010'' and in its place add ''054628''.

§ 520.441 [Amended]

■ 5. In paragraph (b)(3) of § 520.441, remove ''000010'' and in its place add ''054628''.

§ 520.443 [Amended]

■ 6. In paragraph (b) of § 520.443, remove ''000010'' and in its place add ''054628''.

§ 520.580 [Amended]

■ 7. In paragraph (b)(2), remove ''000010 and 000061'' and in its place add ''Nos. 000061 and 054628''.

§ 520.600 [Amended]

■ 8. In paragraph (c) of § 520.600, remove ''000010'' and in its place add ''054628''.

§ 520.622a [Amended]

■ 9. In paragraph (a)(6) of § 520.622a, remove ''000010'' and in its place add ''054628''.

§ 520.622b [Amended]

■ 10. In paragraph (c)(2) of § 520.622b, remove ''000010'' and in its place add ''054628''.

§ 520.622c [Amended]

■ 11. In paragraph (b)(6) of § 520.622c, remove ''000010'' and in its place add ''054628''.

§ 520.763a [Amended]

■ 12. In § 520.763a, remove and reserve paragraph (a); in paragraph (c), remove ''000010'' and in its place add ''054628''; and remove paragraph (e).

§ 520.763b [Amended]

■ 13. In § 520.763b, remove and reserve paragraph (a); and in paragraph (c), remove ''000010'' and in its place add ''054628''.

§ 520.763c [Amended]

■ 14. In paragraph (b) of § 520.763c, remove ''000010'' and in its place add ''054628''; and remove and reserve paragraph (c).

§ 520.1408 [Amended]

■ 15. In paragraph (b) of § 520.1408, remove ''000010'' and in its place add ''054628''; and remove and reserve paragraph (c).

§ 520.1660d [Amended]

■ 16. In § 520.1660d:
■ a. In paragraph (b)(3), remove ''000010'' and in its place add ''054628''.
■ b. In paragraph (d)(1)(ii)(A)(*3*), remove ''000010'' and in its place add ''054628''.
■ c. In paragraph (d)(1)(ii)(B)(*3*), remove ''000010'' and in its place add ''054628''.
■ d. In paragraph (d)(1)(ii)(C)(*3*), remove ''000010'' and in its place add ''054628''.

§ 520.1720a [Amended]

■ 17. In paragraph (b)(2) of § 520.1720a, remove ''000010 and 000859'' and in its place add ''000859 and 054628''.

§ 520.1900 [Amended]

■ 18. In paragraph (b) of § 520.1900, remove ''000010'' and in its place add ''054628''; and in paragraphs (c)(1), (c)(2), and (c)(3), remove the footnote.

§ 520.2220a [Amended]

■ 19. In paragraph (a)(1) of § 520.2220a, remove ''000010, 000069, 000859, 054925, and 057561'' and in its place add ''000069, 000859, 054628, 054925, and 057561''.

§ 520.2345d [Amended]

■ 20. In paragraph (b)(2) of § 520.2345d, remove ''000010'' and in its place add ''054628''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.1044 [Amended]

■ 22. In paragraph (b)(3) of § 522.1044, remove ''000010'' and in its place add ''054628''.

§ 522.1222a [Amended]

■ 23. In paragraph (b) of § 522.1222a, remove ''000010, 000859, 061690, 026637, and 063286'' and in its place add ''000859, 026637, 054628, 061690, and 063286''.

§ 522.1410 [Amended]

■ 24. In paragraph (b) of § 522.1410, remove ''000010'' and in its place add ''054628''.

§ 522.1662a [Amended]

■ 25. In paragraphs (a)(2), (b)(2), (g)(2), and (h)(2) of § 522.1662a, remove ''000010'' and in its place add ''054628''.

■ 26. In § 522.1680, revise the section heading to read as set forth below; and in paragraph (b), remove ''000010, 000856, 000859, and 061623'' and in its place add ''000856, 000859, 054628, and 061623''.

§ 522.1680 Oxytocin.

* * * * *

■ 27. In § 522.1720, revise the section heading to read as set forth below; and in paragraph (b)(2), remove ''000010'' and in its place add ''054628''.

§ 522.1720 Phenylbutazone.

* * * * *

■ 28. In § 522.2220, revise the section heading as set forth below; and in paragraph (c)(2), remove ''000010'' and in its place add ''054628''.

§ 522.2220 Sulfadimethoxine.

* * * * *

■ 29. In § 522.2424, revise the section heading as set forth below; and in paragraph (b), remove ''000010 and 000856'' and in its place add ''000856 and 054628''; and remove paragraph (c)(4).

§ 522.2424 Sodium thiamylal.

* * * * *

§ 522.2483 [Amended]

■ 30. In paragraph (b) of § 522.2483, remove ''000010'' and in its place add ''054628''.

§ 522.2662 [Amended]

■ 31. In paragraph (b)(1) of § 522.2662, remove ''000010'' and in its place add ''054628''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1580b [Amended]

■ 33. In paragraph (b)(1) of § 524.1580b, remove ''000010, 000069, 050749, 054925, 058005, and 061623'' and in its place add ''000069, 050749, 054628, 054925, 058005, and 061623''.

§ 524.1580c [Amended]

■ 34. In paragraph (b) of § 524.1580c, remove ''000010 and 000069'' and in its place add ''000069 and 054628''.

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 35. The authority citation for 21 CFR part 526 continues to read as follows:

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

§ 526.1696b [Amended]

■ 36. In paragraph (b) of § 526.1696b, remove ''000010'' and in its place add ''054628''.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.1044a [Amended]

■ 38. In paragraph (b) of § 529.1044a, remove ''000010, 000061, 000856, 000859 057561, 058005, and 061623'' and in its place add ''000061, 000856, 000859, 054628, 057561, 058005, and 061623''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.205 [Amended]

■ 40. In paragraph (a) of § 558.205, remove ''000010'' and in its place add ''054628''.

Dated: March 26, 2013.

Steven D. Vaughn,

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

[FR Doc. 2013–07542 Filed 4–8–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Parts 581, 584, and 585

RIN 3141–AA47

Appeal Proceedings Before the Commission

AGENCY: National Indian Gaming Commission, Interior.

ACTION: Final rule.

SUMMARY: The National Indian Gaming Commission (NIGC or Commission) is revising its appeals regulations to include, amongst the appealable actions, the Chair's decisions to approve or object to a tribal gaming regulatory authority's adoption of alternate standards from those required by the