of the following sizes, whichever is greater:

(1) At least one-quarter as large as the size of the most prominent printed matter on the PDP, or

(2) At least as large as the size of the ''Drug Facts'' title, as required in § 201.66(d)(2). The new warnings information statement must remain on the PDP of the drug product for at least 1 year from the date the product is initially introduced into interstate commerce.

* * * * *

Dated: November 17, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–28296 Filed 11–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 558

[Docket No. FDA–2009–N–0665]

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 29 new animal drug applications (NADAs) and 2 abbreviated new animal drug applications (ANADAs) from Intervet, Inc., to Schering-Plough Animal Health Corp.

DATES: This rule is effective November 25, 2009.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8307, e-mail: *david.newkirk@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, has informed FDA that it has transferred ownership of, and all rights and interest in, the following 29 approved NADAs and 2 approved ANADAs to Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901: NADA 034–478, 034–621, 045–188, 102–380, 104–494, 111–278, 120–648, 121–473, 128–620, 131–310, 131–675, 132–872, 137–600, 138–612, 139–189, 140–856, 140–897, 140–927, 140–954, 140–992, 141–222, 141–236, 141–258, 141–269, 141–276, 141–278, 141–280, 141–282, 141–286; ANADA 200–134 and 200–239. Accordingly, the agency is amending the regulations in 21 CFR parts 520, 522 (21 CFR part 522), and 558 to reflect the transfer of ownership. In addition, § 522.1081 is being revised to reflect a current format.

Following these changes of sponsorship, Intervet, Inc., is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for Intervet, Inc.

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 and 522

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, 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 ''Intervet, Inc.''; and in the table in paragraph (c)(2), remove the entry for ''057926''.

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.

§ 520.48 [Amended]

■ 4. In paragraph (b) of § 520.48, remove ''057926'' and in its place add ''000061''.

§ 520.905a [Amended]

■ 5. In paragraph (b) of § 520.905a, remove ''057926'' and in its place add ''000061''.

§ 520.905b [Amended]

■ 6. In paragraph (b) of § 520.905b, remove ''057926'' and in its place add ''000061''.

§ 520.905c [Amended]

■ 7. In paragraph (b) of § 520.905c, remove ''057926'' and in its place add ''000061''.

§ 520.905d [Amended]

■ 8. In paragraph (b)(1) of § 520.905d, remove ''057926'' and in its place add ''000061''.

§ 520.905e [Amended]

■ 9. In paragraph (b) of § 520.905e, remove ''057926'' and in its place add ''No. 000061''.

§ 520.1010 [Amended]

■ 10. In paragraph (b)(2) of § 520.1010, remove ''057926'' and in its place add ''000061''.

§ 520.1200 [Amended]

■ 11. In paragraph (b) of § 520.1200, remove ''057926'' and in its place add ''000061''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.246 [Amended]

■ 13. In paragraph (b)(3) of § 522.246, remove ''057926'' and in its place add ''000061''.

§ 522.1010 [Amended]

■ 14. In paragraph (b)(4) of § 522.1010, remove ''057926'' and in its place add ''000061''.

§ 522.1078 [Amended]

■ 15. In paragraph (b) of § 522.1078, remove ''Nos. 050604, 057926, and 059130'' and in its place add ''Nos. 000061, 050604, and 059130''.

§ 522.1079 [Amended]

■ 16. In paragraph (b) of § 522.1079, remove ''057926'' and in its place add ''000061''.

■ 17. Revise § 522.1081 to read as follows:

§ 522.1081 Chorionic gonadotropin.

(a) *Specifications.* Each vial contains 5,000, 10,000 or 20,000 USP units of lyophilized powder for constitution with accompanying diluent to a 10-milliliter solution.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) Nos. 000402 and 053501 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B) and (d)(1)(i)(C) of this section.

(2) Nos. 058639 and 063323 for use as in paragraphs (d)(1)(i)(A) and (d)(1)(i)(B) of this section.

(3) No. 000061 for use as in paragraphs (d)(1)(i)(A) and (d)(2) of this section.

(c) *Related tolerances.* See § 556.304 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* As a single dose. Dosage may be repeated in 14 days if the animal's behavior or examination of the ovaries *per rectum* indicates retreatment.

(A) 10,000 USP units by intramuscular injection.

(B) 500 to 2,500 USP units by intrafollicular injection.

(C) 2,500 to 5,000 USP units by intravenous injection.

(ii) *Indications for use.* For parenteral use in cows for treatment of nymphomania (frequent or constant heat) due to cystic ovaries.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Finfish*—(i) *Amount.* 50 to 510 IU per pound of body weight for males, 67 to 1,816 IU per pound of body weight for females, by intramuscular injection. Up to three doses may be administered.

(ii) *Indications for use.* An aid in improving spawning function in male and female brood finfish.

(iii) *Limitations.* In fish intended for human consumption, the total dose administered per fish (all injections combined) should not exceed 25,000 IU chorionic gonadotropin. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1160 [Amended]

■ 18. In paragraph (b) of § 522.1160, remove ''057926'' and in its place add ''000061''.

§ 522.2476 [Amended]

■ 19. In paragraph (a)(2) of § 522.2476, remove ''057926'' and in its place add ''000061''.

§ 522.2477 [Amended]

■ 20. In paragraph (b)(2) of § 522.2477, remove ''057926'' and in its place add ''000061''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.258 [Amended]

■ 22. In paragraph (b) of § 558.258, remove ''057926'' and in its place add ''000061''; and in the tables in paragraphs (e)(1) through (e)(5), in the ''Sponsor'' column, remove ''057926'' where it occurs and in its place add ''000061''.

§ 558.665 [Amended]

■ 23. In paragraph (b) of § 558.665, remove ''057926'' and in its place add ''000061''; and in the table in paragraph (e), in the ''Sponsor'' column, remove ''057926'' where it occurs and in its place add ''000061''.

Dated: November 19, 2009.

Steven D. Vaughn,

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

[FR Doc. E9–28217 Filed 11–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Parts 41 and 42

[Public Notice 6798]

Visas: Documentation of Immigrants and Nonimmigrants—Visa Classification Symbols

AGENCY: State Department.

ACTION: Final rule.

SUMMARY: The Department is amending its regulations to add new classification symbols to the immigrant and nonimmigrant classification tables. This amendment is necessary to implement legislation that created additional immigrant and nonimmigrant classifications as described herein. Additionally, the Department is amending or removing existing classifications that have changed as a result of new legislation or the expiration of legislative provisions that had temporarily authorized them.

DATES: This rule is effective November 25, 2009.

FOR FURTHER INFORMATION CONTACT: Emily C. Cooperman, Legislation and Regulations Division, Visa Services, U.S. Department of State, Washington, DC 20520–0106, phone (202) 663–1203.

SUPPLEMENTARY INFORMATION:

Which new immigrant classification symbol is being added?

A new immigrant classification for qualifying family members of U1 Nonimmigrant Victim of Criminal Activity, adjustment of status cases for: Spouse, SU2; Child, SU3; and Parent, SU5.

What is the background for the new immigrant classifications (SU2, SU3, SU5) for qualifying family members of U1 Nonimmigrants?

Under INA 245(m)(3), upon approval of adjustment of the status of a U1 principal alien, the Secretary of Homeland Security may approve a petition for an immigrant visa for a spouse (SU2), a child (SU3), or in the case of an alien child, a parent (SU5) who did not receive a nonimmigrant visa under section 101(a)(15)(U)(ii) if the Secretary of Homeland Security considers such approval necessary to avoid extreme hardship. To request approval of immigrant visa status for such a relative, the principal alien must file with U.S. Citizenship and Immigration Services (USCIS) a Form I–929, Petition for Qualifying Family Member of a U1 Nonimmigrant. Upon approval of the petition, beneficiaries may apply for an immigrant visa at a visa processing post overseas.

Which immigrant classification is being amended due to new legislation?

Certain Iraqis (and Afghanis) employed by or on behalf of the United States Government in Iraq (and Afghanistan), SQ1; Spouse SQ2 and Child SQ3.

What is the background for the amended immigrant visa classifications SQ1, SQ2, SQ3?

In addition to Iraqis employed by or on behalf of the United States Government in Iraq, section 1244 of Public Law 110–181, section 602(b) of Division F, Title IV, of the Omnibus Appropriations Act, 2009, Public Law 111–8, authorizes SQ1 status for an Afghan national who has been employed by or on behalf of the United States Government in Afghanistan on or after October 7, 2001, for a period of not less than one year; has provided faithful and valuable service to the United States Government, which is documented in a positive recommendation or evaluation from the alien's senior supervisor; has been determined by the Chief of Mission (COM) or the COM's designee to have experienced, or be experiencing an ongoing serious threat as a consequence of the employment by or on behalf of the U.S. Government. Further, the alien must clear a background check and appropriate screening as determined by the Department of Homeland Security, be otherwise eligible to receive an immigrant visa, and be otherwise admissible to the United States for permanent residence, except that, in the determination of such admissibility, the