industry of the business concern combined with its affiliates.

* * * * *

Dated: July 16, 2009.

Karen Gordon Mills,

Administrator.

[FR Doc. E9–17323 Filed 7–17–09; 11:15 am]

BILLING CODE 8025–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 522

[Docket No. FDA–2009–N–0270]

Animal Drugs, Feeds, and Related Products; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations by removing those portions that reflect approval of two new animal drug applications (NADAs) and an abbreviated new animal drug application (ANADA). In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of these NADAs and ANADA.

DATES: This rule is effective August 3, 2009.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9079, e-mail: *john.bartkowiak@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The following sponsors have requested that FDA withdraw approval of the two NADAs and ANADA listed in table 1 of this document because the products are no longer manufactured or marketed:

TABLE 1.

Sponsor	NADA/ANADA Number Product (Drug)	21 CFR Cite Affected (Sponsor Drug Labeler Code)
Wellmark International, 1501 East Woodfield Rd., suite 200, West Schaumburg, IL 60173	NADA 141–162 Zodiac Fleatrol Flea Caps (S-methoprene)	520.1390 (011536)
IDEXX Pharmaceuticals, Inc., 7009 Albert Pick Rd., Greensboro, NC 27409	NADA 141–178 NAVIGATOR Paste (nitazoxanide)	520.1498 (065274)
Abbott Laboratories, North Chicago, IL 60064	ANADA 200–279 KETAFLO Injection (ketamine HCl, USP)	522.1222a (000074)

In a notice published elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADAs 141–162 and 141–178, and ANADA 200–279, and all supplements and amendments thereto, are withdrawn, effective August 3, 2009. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect the withdrawal of approval.

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 in 21 CFR Parts 520 and 522

Animal drugs.

■ 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 520 and 522 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.1390 [Removed]

■ 2. Remove § 520.1390.

§ 520.1498 [Removed]

■ 3. Remove § 520.1498.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.1222a [Amended]

■ 5. In paragraph (b) of § 522.1222a, remove ''000074,''.

Dated: July 14, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9–17409 Filed 7–21–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 524

[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 three new animal drug applications (NADAs) and one abbreviated new animal drug application (ANADA) from Virbac AH, Inc., to Cross Vetpharm Group Ltd.

DATES: This rule is effective July 22, 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: Virbac AH, Inc., 3200 Meacham Blvd., Ft.

Worth, TX 76137, has informed FDA that it has transferred ownership of, and all rights and interest in, the following three approved NADAs and one approved ANADA to Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland:

Application No. (NADA/ANADA)	21 CFR Section	Product Name
007–076	520.2325a	Sulfa-Nox (sulfaquinoxaline) Liquid
008–244	520.2325a	Sulfa-Nox (sulfaquinoxaline) Concentrate
049–729	520.2261a	PURINA Sulfa (sulfamethazine)
200–318	524.1193	VIRBAMEC (ivermectin) Pour-On

Accordingly, the agency is amending the regulations in 21 CFR 520.2261a, 520.2325a, and 524.1193 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 in 21 CFR Parts 520 and 524

Animal drugs.

■ 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 520 and 524 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.2261a [Amended]

■ 2. In paragraph (a) of § 520.2261a, remove ''051311 and 053501'' and in its place add ''053501 and 061623''.

§ 520.2325a [Amended]

■ 3. In paragraph (a)(2) of § 520.2325a, remove ''051311'' and in its place add ''061623''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1193 [Amended]

■ 5. In paragraph (b) of § 524.1193 remove ''051311'' and in numerical sequence add ''061623''.

Dated: July 14, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9–17356 Filed 7–21–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice: 6676]

Foreign Officials: Definition of Immediate Family Members, as Amended

AGENCY: State Department.

ACTION: Final rule.

SUMMARY: As authorized the Immigration and Nationality Act this rule amends the definition of ''immediate family'' for the Foreign Government Official nonimmigrant visa category.

DATES: *Effective Date:* This rule is effective July 22, 2009.

FOR FURTHER INFORMATION CONTACT: Lauren A. Prosnik, Legislation and Regulations Division, Visa Services, Department of State, 2401 E Street, NW., Room L–603D, Washington, DC 20520–0106, (202) 663–1202, e-mail (*ProsnikLA@state.gov*).

SUPPLEMENTARY INFORMATION:

Why is the Department promulgating this rule?

The Secretary of State has the authority and responsibility for the execution of the foreign policy of the United States. In the exercise of this authority and responsibility, this rule amends the definition of ''immediate family'' for the Foreign Government Official category of nonimmigrants as authorized by section 101(a)(15)(A) of the Immigration and Nationality Act [8 U.S.C 1101]. The term ''immediate family'' previously required that immediate family members other than the spouse and unmarried sons and daughters be related to the principal or spouse by blood, marriage or adoption. The definition now includes, upon authorization from the Department on a case by case basis, any other alien who is not a member of some other household; will reside regularly in the household of the principal alien; and is recognized as a family member of the principal alien by the sending Government as demonstrated by eligibility for rights and benefits from that Government, such as the issuance of a diplomatic or official passport or travel or other allowances. This will allow the Department greater flexibility in responding to requests by foreign governments to issue a diplomatic visa to a person who regularly resides with and is a member of the household of a qualified principal alien and is considered by the principal alien and the sending Government to be a member of the immediate family of the principal alien.

Regulatory Findings

Administrative Procedure Act

This regulation involves a foreign affairs function of the United States and, therefore, in accordance with 5 U.S.C. 553(a)(1), is not subject to the rule making procedures set forth at 5 U.S.C. 553.

Regulatory Flexibility Act/Executive Order 13272: Small Business

Because this final rule is exempt from notice and comment rulemaking under 5 U.S.C. 553, it is exempt from the regulatory flexibility analysis requirements set forth at sections 603 and 604 of the Regulatory Flexibility Act (5 U.S.C. 603 and 604). Nonetheless, consistent with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Department certifies that this rule will not have a significant economic impact on a substantial number of small entities. This regulation does not affect any small entities, as defined in 5 U.S.C. 601(6).

The Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 (UFMA), Public Law 104–4, 109 Stat. 48, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of $100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure, nor will it significantly or uniquely affect small governments.