

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.

The Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking under the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104-121. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign based companies in domestic and import markets.

Executive Order 12866

The Department of State has reviewed this regulation to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866 and has determined that the benefits of the regulation justify its costs. The Department does not consider the regulation to be an economically significant action within the scope of section 3(f)(1) of the Executive Order since it is not likely to have an annual effect on the economy of \$100 million or more or to adversely affect in a material way the economy, a sector of the economy, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities.

Executive Orders 12372 and 13132: Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Nor will the rule have federalism implications warranting the application of Executive Orders No. 12372 and No. 13132.

Executive Order 12988: Civil Justice Reform

The Department has reviewed the legislation in light of sections 3(a) and 3(b)(2) of Executive Order No. 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Paperwork Reduction Act

This rule does not impose information collection requirements under the provisions of the Paperwork Reduction Act, 44 U.S.C., Chapter 35.

List of Subjects in 22 CFR Part 41

Aliens, Foreign officials, Immigration, Nonimmigrants, Passports and visas.

■ For the reasons set forth in the preamble, the Department of State amends 22 CFR part 41 as follows:

PART 41—[AMENDED]

■ 1. Revise paragraph (a)(3) of § 41.21 is to read as follows:

§ 41.21 Foreign Officials—General.

(a) * * *

(3) *Immediate family*, as used in INA 101(a)(15)(A), 101(a)(15)(G), and 212(d)(8), and in classification under the NATO-1 through NATO-5 visa symbols, means the spouse and unmarried sons and daughters, whether by blood or adoption, who are not members of some other household, and who will reside regularly in the household of the principal alien. Under the INA 101(a)(15)(A) and 101(a)(15)(G) visa classifications, “immediate family” also includes individuals who:

- (i) Are not members of some other household;
- (ii) Will reside regularly in the household of the principal alien;
- (iii) Are recognized as immediate family members of the principal alien by the sending Government as demonstrated by eligibility for rights and benefits, such as the issuance of a diplomatic or official passport, or travel or other allowances; and
- (iv) Are individually authorized by the Department.

* * * * *

Dated: July 14, 2009.

Michael D. Kirby,

Acting Assistant Secretary for Consular Affairs, Department of State.

[FR Doc. E9-17262 Filed 7-21-09; 8:45 am]

BILLING CODE 4710-06-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

[WV-115-FOR; OSM-2009-0006]

West Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Interim rule with request for comments.

SUMMARY: We are approving, on an interim basis, an amendment to the West Virginia regulatory program (the West Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). West Virginia revised its Surface

Coal Mining and Reclamation Act to effect changes concerning its alternative bonding system. The tax provisions of the amendment are intended to increase and extend the special reclamation tax, subject to biennial review by the legislature, and remove the additional tax. We are approving the increase and extension of the special reclamation tax, at the rate of fourteen and four-tenths cents per ton of clean coal mined, for deposit in the Special Reclamation Fund and the Special Reclamation Water Trust Fund, on an interim basis, with our approval becoming effective upon publication of this interim rule.

DATES: *Effective Date:* This rule is effective July 22, 2009. *Comment Date:* We will accept written comments until 4 p.m., local time August 21, 2009. If requested, we will hold a public hearing on August 17, 2009. We will accept requests to speak until 4 p.m., local time on August 6, 2009.

ADDRESSES: You may submit written comments by any of the following two methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. The proposed rule has been assigned Docket ID: OSM-2009-0006. If you would like to submit comments through the Federal eRulemaking Portal, go to <http://www.regulations.gov> and do the following. Click on the “Advanced Docket Search” button on the right side of the screen. Type in the Docket ID OSM-2009-0006 and click the “Submit” button at the bottom of the page. The next screen will display the Docket Search Results for the rulemaking. If you click on OSM-2009-0006, you can view the proposed rule and submit a comment. You can also view supporting material and any comments submitted by others.

- *Mail/Hand Delivery:* Mr. Roger W. Calhoun, Director, Charleston Field Office, Office of Surface Mining Reclamation and Enforcement, 1027 Virginia Street, East, Charleston, West Virginia 25301. Please include the rule identifier (WV-115-FOR) with your written comments.

Instructions: All submissions received must include the agency Docket ID (OSM-2009-0006) for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see “IV. Public Comment Procedures” in the **SUPPLEMENTARY INFORMATION** section of this document. You may also request to speak at a public hearing by any of the methods listed above or by contacting the individual listed under **FOR FURTHER INFORMATION CONTACT**.