(1) A civil penalty not to exceed $10,000 may be imposed on any person who violates, or attempts to violate, any order or regulation issued under the Act.

(2) A criminal penalty not to exceed $50,000, or;

(i) If a natural person, imprisonment for not more than 10 years, or both, may be imposed for willful violation of any license, order, or regulation issued under the Act.

(ii) If a corporation, imprisonment for not more than 10 years, or both may be imposed on any officer, director, or agent of the corporation for willful violation of any license, order, or regulation issued under the Act.

(b) *Exports of other than rough diamonds.* Any person who violates any provisions of this part, except for violations of the provisions relating to delayed filing of documents under bond as provided by § 30.24 and violations of section 8 of Public Law 108–19, the Clean Diamond Trade Act, shall be liable to the United States in an amount not exceeding $1,000 for each violation, as authorized by section 305, chapter 9, title 13 U.S.C.

Dated: October 10, 2003.

Charles Louis Kincannon,

Director, Bureau of the Census.

[FR Doc. 03–26282 Filed 10–17–03; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 529

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 12 approved new animal drug applications (NADAs) and 1 abbreviated new animal drug application (ANADA) from Anthony Products Co. to Cross Vetpharm Group, Ltd.

DATES: This rule is effective October 20, 2003.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *dnewkirk@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006, has informed FDA that it has transferred ownership of, and all rights and interest in, the following 12 approved NADAs and one approved ANADA to Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.

Application No.	21 CFR Section	Trade Name
NADA 046–780	522.1720	PHEN–BUTA–VET (phenylbutazone) Injection
NADA 096–671	522.1720	PHEN–BUTA–VET (phenylbutazone) Injection
NADA 096–672	520.1720a	PHEN–BUTA–VET (phenylbutazone) Tablets
NADA 098–288	522.1883	PREDNIS–A–VET (prednisolone sodium phosphate) Injection
NADA 099–604	522.540	DEX–A–VET (dexamethasone sodium phosphate) Injection
NADA 099–605	522.540	DEX–A–VET (dexamethasone sodium phosphate) Injection
NADA 099–606	522.540	DEXAMETH–A–VET (dexamethasone) Injection
NADA 099–607	522.540	DEXAMETH–A–VET (dexamethasone) Injection
NADA 118–550	522.1010	FUROS–A–VET (furosemide) Injection
NADA 119–141	522.1962	TRANQUAZINE (promazine hydrochloride) Injection
NADA 138–405	522.2063	Pyrilamine Maleate Injection
NADA 140–583	522.480	ACTH Gel
ANADA 200–115	529.1044a	GENTAMEX 100 (gentamicin sulfate)

Accordingly, the agency is amending the regulations in 21 CFR 520.1720a, 522.480, 522.540, 522.1010, 522.1720, 522.1883, 522.1962, 522.2063, and 529.1044a to reflect the transfer of ownership. Sections 522.1883 and 522.1962 are also being revised to reflect a current format.

Following these changes of sponsorship, Anthony Products Co. is no longer the sponsor of an approved application. Accordingly, § 510.600(c) is being amended to remove the entries for Anthony Products Co.

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, and 529

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 510, 520, 522, and 529 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. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''Anthony Products Co.'' and in the table in paragraph (c)(2) by removing the entry for ''000864''.

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.

§ 520.1720a [Amended]

■ 4. Section 520.1720a *Phenylbutazone tablets and boluses* is amended in paragraph (b)(3) by removing ''000864''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.480 [Amended]

■ 6. Section 522.480 *Repository corticotropin injection* is amended in paragraph (b)(2) by removing ''000864'' and by adding in its place ''061623''.

§ 522.540 [Amended]

■ 7. Section 522.540 *Dexamethasone injection* is amended in paragraphs (b)(2)(i) and (c)(2) by removing ''000864'' and by adding in its place ''061623''.

§ 522.1010 [Amended]

■ 8. Section 522.1010 *Furosemide* is amended in paragraph (b)(2) by removing ''000864'' and by adding in its place ''061623''.

§ 522.1720 [Amended]

■ 9. Section 522.1720 *Phenylbutazone injection* is amended in paragraph (b)(1) by removing ''and 059130'' and by adding in its place ''059130, and 061623''; in paragraph (b)(2) by removing ''Nos. 000010 and 000864'' and by adding in its place ''No. 000010''; and by removing paragraph (b)(4).

■ 10. Section 522.1883 is revised to read as follows:

§ 522.1883 Prednisolone sodium phosphate.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) prednisolone sodium phosphate (equivalent to 14.88 mg of prednisolone).

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer intravenously in a dosage of 2 1/2 to 5 mg per pound of body weight, initially for shock and shock-like states, followed by equal maintenance doses at 1-, 3-, 6-, or 10-hour intervals as determined by the condition of the animal.

(2) *Indications for use.* Administer when a rapid adrenal glucocorticoid and/or anti-inflammatory effect is necessary.

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

■ 11. Section 522.1962 is amended:
■ a. By removing ''injection'' from the heading;
■ b. By removing footnote 1;
■ c. In paragraph (b) by removing ''000864'' and by adding in its place ''061623'';
■ d. By removing paragraphs (c)(3) and (c)(4);
■ e. By revising paragraphs (a) and (c)(2); and
■ f. By adding a heading to (c)(1).
■ The amendments read as follows:

§ 522.1962 Promazine hydrochloride.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) promazine hydrochloride.

* * * * *

(c) * * *

(1) *Amounts and indications for use.*

(i) * * *

* * * * * *

(2) *Limitations.* Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2063 [Amended]

■ 12. Section 522.2063 *Pyrilamine maleate injection* is amended in paragraph (b) by removing ''000864'' and by adding in its place ''061623''.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.1044a [Amended]

■ 14. Section 529.1044a *Gentamicin sulfate intrauterine solution* is amended in paragraph (b) by removing ''000864, 057561, and 059130'' and by adding in its place ''057561, 059130, and 061623''.

Dated: October 2, 2003.

Steven D. Vaughn,

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

[FR Doc. 03–26336 Filed 10–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. 2003–P–021]

RIN 0651–AB61

January 2004 Revision of Patent Cooperation Treaty Application Procedure

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (Office) is amending the rules of practice to conform them to certain amendments made to the Regulations under the Patent Cooperation Treaty (PCT) that will take effect on January 1, 2004. These amendments will result in the addition of a written opinion in PCT Chapter I, as well as a simplification of PCT designations and the PCT fee structure. In addition, the Office is adjusting the transmittal, search, and international preliminary examination fees for international applications filed under the PCT to be more closely aligned with the actual average costs of processing a PCT application and conducting a PCT search and international preliminary examination under the new process.

EFFECTIVE DATE: January 1, 2004.

FOR FURTHER INFORMATION CONTACT: Richard R. Cole, Legal Examiner, Office of PCT Legal Administration (OPCTLA) directly by telephone at (703) 305–6639, or by facsimile at (703) 308–6459.

SUPPLEMENTARY INFORMATION: During the September-October 2002 meeting of the Governing Bodies of the World Intellectual Property Organization (WIPO), the PCT Assembly adopted various amendments to the Regulations under the PCT that enter into force on January 1, 2004. The amended PCT Regulations were published in the PCT Gazette of December 5, 2002 (49/2002), in Section IV, at pages 25004–61. The purposes of these amendments are to: (1) Improve coordination of international search (Chapter I of the PCT) and international preliminary examination (Chapter II of the PCT) through the provision of an enhanced international search and preliminary examination system; (2) simplify the PCT by changing the concept and operation of the designation system and the fee system; and (3) simplify signature and other filing requirements.

Enhanced International Search and Preliminary Examination System: Under the enhanced international search and