

(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.

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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:

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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.