generic copy of Merial's HEARTGARD Plus Chewables, approved under NADA 140–971. ANADA 200–338 is approved as of August 13, 2003, and 21 CFR 520.1196 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Heska Corp. is not currently listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 Part 520*

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 and 520 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.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Heska Corp.'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''063604'' to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

* * * * *

(c) * * *

(1) * * *

| Firm name and address | Drug labeler code |
|---|---|
| * * * * * | |
| Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525. | 063604 |
| * * * * * | |

(2) * * *

| Drug labeler code | Firm name and address |
|---|---|
| * * * * * | |
| 063604 ..... | Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525 |
| * * * * * | |

## 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.

■ 4. Section 520.1196 is amended by revising paragraph (b) to read as follows:

**§ 520.1196 Ivermectin and pyrantel pamoate chewable tablets.**

* * * * *

(b) *Sponsors.* See Nos. 050604, 051311, and 063604 in § 510.600(c) of this chapter.

* * * * *

Dated: September 15, 2003.

**Linda Tollefson,**

*Deputy Director, Center for Veterinary Medicine.*

[FR Doc. 03–24496 Filed 9–26–03; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 510, 520, and 522

### 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 two new animal drug applications (NADAs) and three abbreviated new animal drug applications (ANADAs) from Delmarva Pharmaceuticals, Inc., to Virbac AH, Inc.

**DATES:** This rule is effective September 29, 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:** Delmarva Laboratories, Inc., 1500 Huguenot Rd., suite 106, Midlothian, VA 23113, has informed FDA that it has transferred ownership of, and all rights and interest in, the following two approved NADAs and three approved ANADAs to Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137:

| Application No. | 21 CFR Section | Trade Name |
|---|---|---|
| NADA 065–492 | 520.88f | ROBAMOX V (amoxicillin trihydrate) Tablets |
| NADA 065–495 | 520.88b | ROBAMOX V (amoxicillin trihydrate) |
| ANADA 200–071 | 522.900 | EUTHASOL Solution |
| ANADA 200–291 | 520.447 | CLINSOL (clindamycin hydrochloride) Liquid |
| ANADA 200–316 | 520.446 | CLINTABS (clindamycin hydrochloride) Tablets |

Accordingly, the agency is amending the regulations in §§ 520.88b, 520.88f, 520.446, 520.447, and 522.900 to reflect the transfer of ownership.

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

■ 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, and 522 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 ''Delmarva Laboratories, Inc.'' and in the table in paragraph (c)(2) by removing the entry for ''059079''.

## 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.

### § 520.88b [Amended]

■ 4. Section 520.88b *Amoxicillin trihydrate for oral suspension* is amended in paragraph (c) by removing ''059079'' and by adding in its place ''051311''.

### § 520.88f [Amended]

■ 5. Section 520.88f *Amoxicillin trihydrate tablets* is amended in paragraph (b) by removing ''059079'' and by adding in its place ''051311''.

### § 520.446 [Amended]

■ 6. Section 520.446 *Clindamycin capsules and tablets* is amended in paragraph (b)(3) by removing ''059079'' and by adding in its place ''051311''.

### § 520.447 [Amended]

■ 7. Section 520.447 *Clindamycin liquid* is amended in paragraph (b)(2) by removing ''059079'' and by adding in its place ''051311''.

## PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

### § 522.900 [Amended]

■ 9. Section 522.900 *Euthanasia solution* is amended in paragraph (b)(1) by removing ''059079'' and by adding in its place ''051311''.

Dated: September 15, 2003.

**Steven D. Vaughn,**

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

[FR Doc. 03–24492 Filed 9–26–03; 8:45 am]

BILLING CODE 4160–01–S

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 520

### Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Suspension

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for oral use of two strengths of pyrantel pamoate suspension in dogs for the management of various internal parasites.

**DATES:** This rule is effective September 29, 2003.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

**SUPPLEMENTARY INFORMATION:** First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200–352 for PRIMEX CANINE (pyrantel pamoate) and PRIMEX CANINE–2X (pyrantel pamoate). PRIMEX CANINE contains 2.27 milligrams (mg) pyrantel base per milliliter (/mL); PRIMEX CANINE–2X contains 4.54 mg pyrantel base/mL. Both products are for oral use in dogs and puppies for the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*); and in dogs, puppies, and lactating bitches to prevent reinfections of *T. canis*. First Priority's PRIMEX CANINE and PRIMEX CANINE–2X are approved as generic copies of Pfizer, Inc.'s RFD Suspension and NEMEX–2 Suspension, respectively, approved under NADA 100–237. ANADA 200–352 is approved as of August 20, 2003, and the regulations are amended in § 520.2043 (21 CFR 520.2043) to reflect the approval. The basis of approval is discussed in the freedom of information summary. In addition, § 520.2043 is being amended to correct the spelling of one of the subject parasites.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 congressional review requirements in 5 U.S.C. 801–808.

**List of Subjects in 21 CFR Part 520**

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 part 520 is amended as follows: