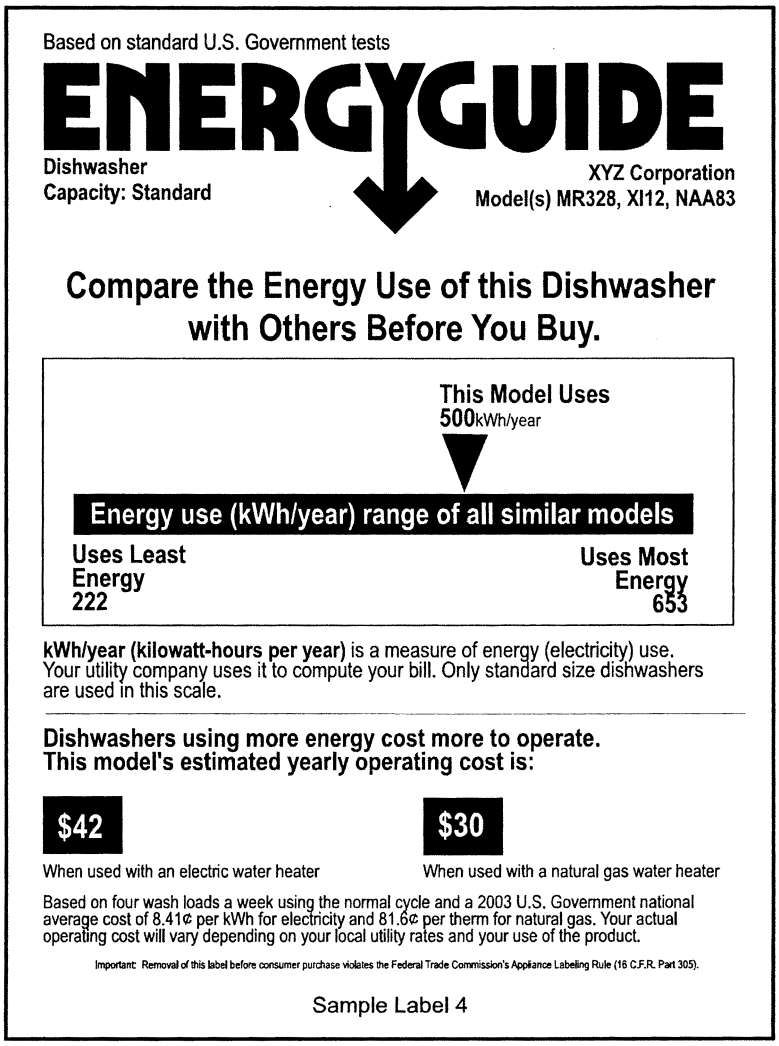

Sample Label 4

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 03–24570 Filed 9–26–03; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

Labeling

CFR Correction

In Title 21 of the Code of Federal Regulations, parts 200 to 299, revised as of April 1, 2003, in the first sentence of the introductory text of § 201.122, on page 54, the phrase '' 'Rx only' '' is removed and the phrase '' 'Caution: For manufacturing, processing, or repacking' '' is added in its place, and the phrase '' 'Caution: Federal law prohibits dispensing without prescription' '' is removed and the phrase '' 'Rx only' '' is added in its place.

[FR Doc. 03–55525 Filed 9–26–03; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Ivermectin and Pyrantel Pamoate Chewable Tablets

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 Heska Corp. The ANADA provides for use of chewable tablets containing ivermectin and pyrantel pamoate for prevention of heartworm disease and for treatment and control of certain gastrointestinal parasites in dogs.

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: Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525, filed ANADA 200–338 that provides for veterinary prescription use of TRI–HEART PLUS (ivermectin and pyrantel pamoate) Chewable Tablets for prevention of canine heartworm disease caused by *Dirofilaria immitis* and for treatment and control of ascarids (*Toxocara canis*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *A. braziliense*, and *Uncinaria stenocephala*) in dogs. Heska Corp.'s TRI–HEART PLUS Chewable Tablets is approved as a

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