Firm name and address	Drug labeler code
* * *	* * * *
Akzo Nobel Surface Chemistry AB, Box 851, S–44485 Stenungsund, Sweden	063765
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
063765	Akzo Nobel Surface Chemistry AB, Box 851, S–44485 Stenungsund, Sweden.
* * *	* * * *

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.

§ 520.1806 [Amended]

4. Section 520.1806 *Piperazine monohydrochloride liquid* is amended in paragraph (b) by removing ''See 017135 and 060594'' and adding in its place ''See Nos. 017135 and 063765''.

Dated: January 21, 1998.

Andrew J. Beaulieau,

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

[FR Doc. 98–4076 Filed 2–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Doxycycline Hyclate

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 a new animal drug application (NADA) filed by Heska Corp. The NADA provides for use of doxycycline hyclate solution for treatment and control of periodontal disease in dogs by application subgingivally to the periodontal pocket(s) of affected teeth.

EFFECTIVE DATE: February 19, 1998.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20857, 301–594–1612.

SUPPLEMENTARY INFORMATION: Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525, filed NADA 141–082, which provides for use of doxycycline hyclate solution for treatment and control of periodontal disease in dogs by application subgingivally to the periodontal pocket(s) of affected teeth. The NADA is approved as of November 19, 1997, and the regulations are amended by adding new 21 CFR 522.778 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, the regulations are amended in § 510.600(c) to add the new sponsor to the list of sponsors of approved applications.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning November 19, 1997, because no active ingredient, including any ester or salt of the active ingredient, has been previously approved in any other application filed under section 512(b)(1) of the act.

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.

List of Subjects in

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 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 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.

2. Section 510.600 is amended in paragraph (c)(1) by alphabetically adding a new entry for ''Heska Corp.'' and 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 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

4. Section 522.778 is added to read as follows:

§ 522.778 Doxycycline hyclate.

(a) *Specifications.* Doxycycline hyclate solution contains 8.5 percent doxycycline activity. A syringe of *N*-methyl-2-pyrrolidone and poly (DL-lactide) mixed with a syringe of doxycycline produces 0.5 milliliter of solution.

(b) *Sponsor.* See 063604 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Apply subgingivally to periodontal pocket(s) of affected teeth.

(ii) *Indications for use.* For treatment and control of periodontal disease.

(iii) *Limitations.* Do not use in dogs less than 1-year old. Use of tetracyclines during tooth development has been associated with permanent discoloration of teeth. Do not use in pregnant bitches. Use in breeding dogs has not been evaluated. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: January 21, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–4077 Filed 2–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 526 and 529

Animal Drugs, Feeds, and Related Products; Cephapirin Sodium for Intramammary Infusion; Redesignation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to redesignate a section of those regulations. A section reflecting approval of an intramammary product is redesignated from certain other dosage form new animal drugs to intramammary dosage forms to reflect the correct designation of the product.

EFFECTIVE DATE: February 19, 1998.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1739.

SUPPLEMENTARY INFORMATION: The animal drug regulations in part 529 (21 CFR part 529) provide for codification of certain other dosage form new animal drugs. The regulations in part 526 (21 CFR part 526) provide for codification of intramammary dosage forms. Cephapirin sodium for intramammary infusion was inadvertently codified as § 529.365. At this time, the animal drug regulations are amended to redesignate § 529.365 as § 526.365.

List of Subjects

21 CFR Parts 526 and 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 526 and 529 are amended as follows:

PART 526—INTRAMAMMARY DOSAGE FORMS

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citations for 21 CFR parts 526 and 529 continue to read as follows:

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

§ 529.365 [Redesignated as § 526.365]

2. Section 529.365 is redesignated as § 526.365.

Dated: February 5, 1998.

Andrew J. Beaulieau,

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

[FR Doc. 98–4081 Filed 2–18–98; 8:45 am]

BILLING CODE 4160–01–F