

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        |
|---|--------------------------|
| * * *<br>Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525<br>* * * | * * *<br>063604<br>* * * |

(2) \* \* \*

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

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