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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

Display Date 10-24-07
Publication Date 10-25-07
Certifier A. Corbin

New Animal Drugs For Use in Animal Feeds; 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 seven approved new animal drug applications (NADAs) from Schering-Plough Animal Health Corp. to Huvepharma AD.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

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: *david.newkirk@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit NJ 07901, has informed FDA that it has transferred ownership of, and all rights and interest in, the following seven approved NADAs to Huvepharma AD, 33 James Boucher Blvd., Sophia 1407, Bulgaria:

| Application No. | Trade name(s) |
|-----------------|--|
| 140-951 | CLINICOX (diclazuril) Type A Medicated Article |
| 141-090 | CLINICOX / STAFAC |
| 141-153 | CLINICOX / BMD |
| 141-158 | CLINICOX / FLAVOMYCIN |
| 141-190 | CLINICOX / BMD / 3-NITRO |
| 141-194 | CLINICOX / BMD |
| 141-195 | CLINICOX / FLAVOMYCIN |

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Accordingly, the agency is amending the regulations in 21 CFR 558.198 to reflect the transfer of ownership.

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 in 21 CFR Part 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

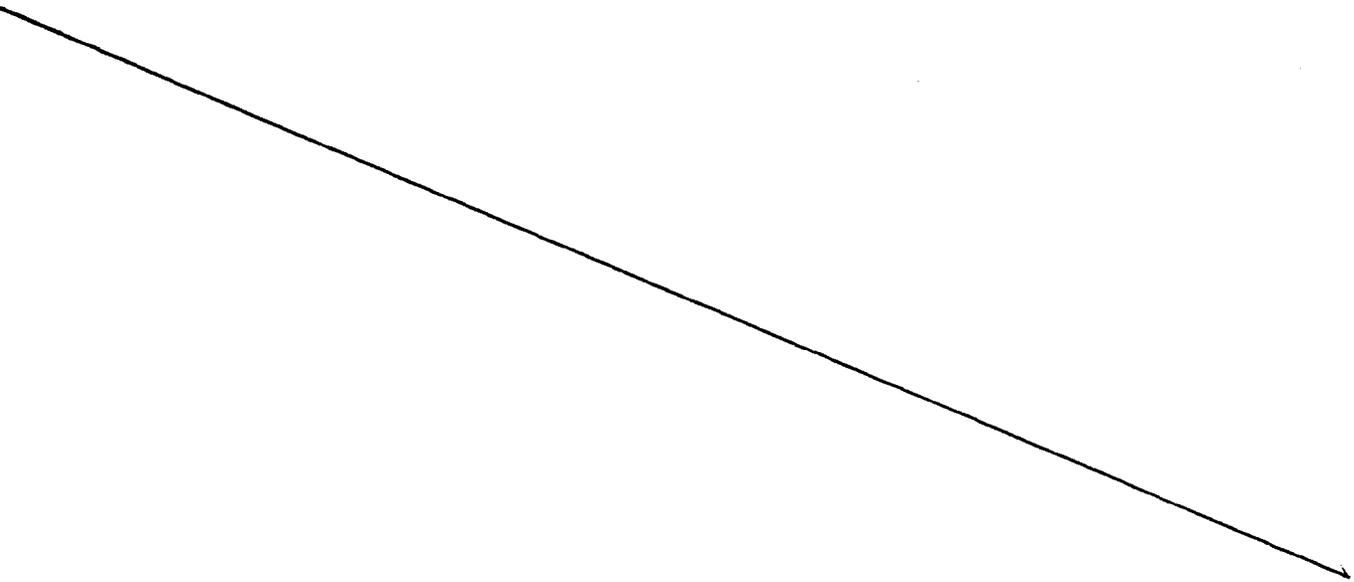
PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.198 [Amended]

■ 2. In § 558.198, in paragraph (b), remove “000061” and in its place add “016592”; and in the tables in paragraphs (d)(1) and (d)(2), in the “Sponsor” column, remove “000061” wherever it occurs and in its place add “016592”.



Dated: 10/17/07

October 17, 2007.

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JD
10/22/07

Bernadette Dunham,
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[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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