

Dme

Display Date	9-2-99
Publication Date	9-3-99
Certifier	M. Bell

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 520**

**Oral Dosage Form New Animal Drugs; Enrofloxacin 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 a supplemental new animal drug application (NADA) filed by Bayer Corp., Agriculture Division, Animal Health. The supplemental NADA provides for an additional tablet size for enrofloxacin tablets used in dogs and cats for the management of diseases associated with bacteria susceptible to enrofloxacin and for the removal of a tablet size no longer marketed.

**EFFECTIVE DATE:** (*Insert date of publication in the Federal Register.*)

**FOR FURTHER INFORMATION CONTACT:** Dennis M. Bensley, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1705.

**SUPPLEMENTARY INFORMATION:** Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed supplemental NADA 140-441 Baytril® tablets (enrofloxacin) that provides for 136-milligram (mg) tablet size in addition to 22.7- and 68.0-mg tablets.

Furthermore, the sponsor stated that the 5.7-mg tablets are no longer marketed and has requested the size be deleted. The supplemental NADA is approved as of August 3, 1999, and the regulations are amended in 21 CFR 520.812(a) to reflect the approval.

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, 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(d)(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 in 21 CFR Part 520**

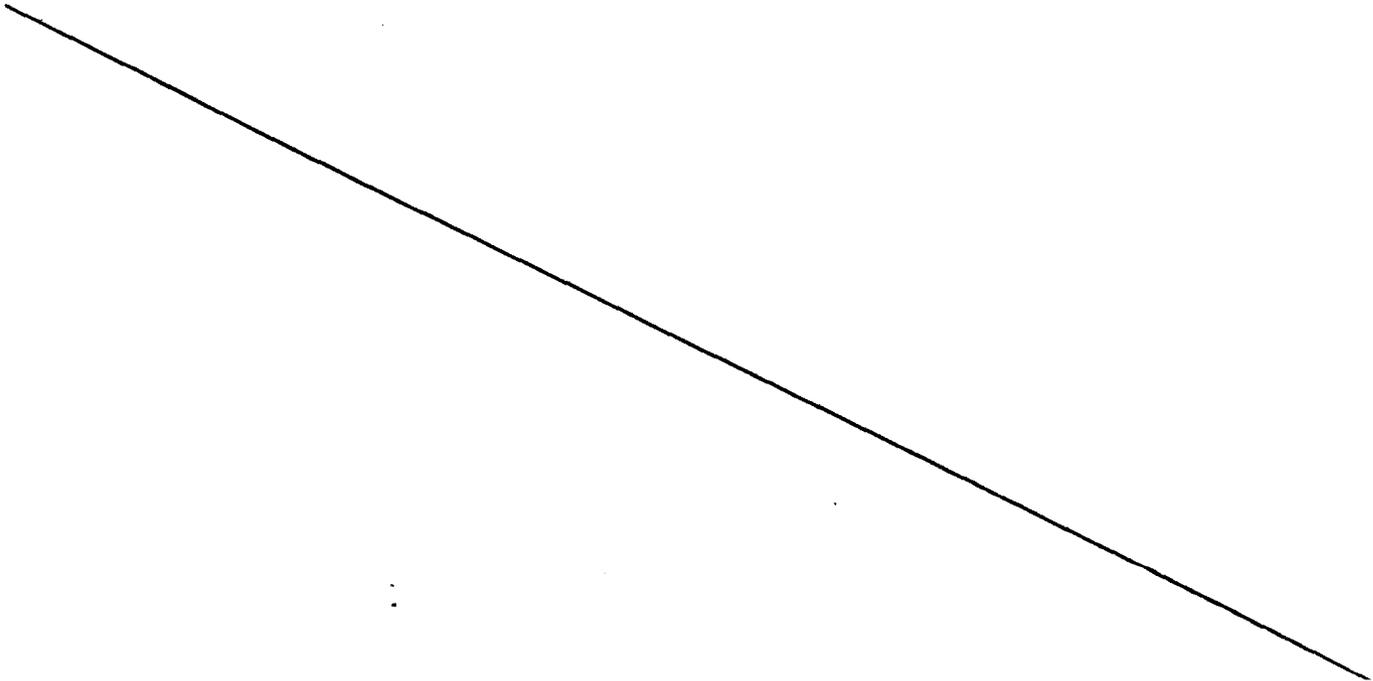
Animal drugs.

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:

**PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

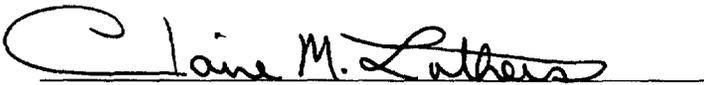


§ 520.812 [Amended]

2. Section 520.812 *Enrofloxacin tablets* is amended in paragraph (a) by removing “5.7, 22.7, or 68.0” and adding in its place “22.7, 68.0, or 136.0” .

Dated: 8/24/99

August 24, 1999



Claire M. Lathers, Director  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

