DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2010–N–0002]

Oral Dosage Form New Animal Drugs; Tetracycline Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 Alpharma, Inc. The supplemental NADA provides for revised labeling for a 25 gram per pound concentration of tetracycline hydrochloride soluble powder used to make medicated drinking water for calves, swine, chickens, and turkeys for the treatment and control of various bacterial diseases.

DATES: This rule is effective March 18, 2010.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., 440 Rte. 22, Bridgewater, NJ 08807, filed a supplement to NADA 65–140 that provides for revised labeling for DURAMYCIN–10 (tetracycline hydrochloride), a soluble powder containing 25 grams of tetracycline hydrochloride per pound used to make medicated drinking water for calves, swine, chickens, and turkeys for the treatment and control of various bacterial diseases. The supplemental application is approved as of January 12, 2010, and the regulations are amended in 21 CFR 520.2345d to reflect the approval.

In addition, FDA has noticed that this approved concentration of tetracycline soluble powder has not been codified for this sponsor. At this time, the regulations are being amended to reflect approval of this product. This change is being made to improve the accuracy of the animal drug regulations.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required. The agency has determined under 21 CFR 25.33 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:


2. In § 520.2345d, revise paragraphs (b)(2) and (b)(3); remove paragraph (b)(4); and redesignate paragraph (b)(5) as paragraph (b)(4) to read as follows:

§ 520.2345d Tetracycline powder.

(b)* * * *

(2) No. 000010: 102.4 and 324 grams per pound as in paragraph (d) of this section.

(3) No. 046573: 25, 102.4, and 324 grams per pound as in paragraph (d) of this section.

Dated: March 5, 2010.

Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

Postal Service

39 CFR Part 111

Eligibility for Commercial Flats Failing Deflection

AGENCY: Postal Service®.

ACTION: Final rule.

SUMMARY: The Postal Service published a proposed rule regarding eligibility for commercial flats failing deflection in the Federal Register on December 14, 2009. This final rule provides revised mailing standards and price eligibility for commercial flats of all classes that fail to meet the deflection standard.


FOR FURTHER INFORMATION CONTACT: Bill Chatfield, 202–268–7278.

SUPPLEMENTARY INFORMATION: This final rule contains modifications to the original proposal, in response to customer comments. The final rule does not include changes to the deflection standards, but to the pricing eligibility. In response to the original deflection proposal and scheduled implementation in May 2009, customers expressed concerns about the potential additional postage due for pieces failing the deflection standards. Based on these concerns and to align with other quality efforts, in December 2009 the Postal Service proposed to change the price eligibilities applicable for pieces that fail the deflection standards.

In this final rule notice we provide background, summary of the comments received, our response to the comments, a summary of the changes and revisions to the applicable prices for pieces that do not meet the deflection standards, followed by changes to the mailing standards in Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM®).

Background

The Postal Service’s final rule for new mailing standards to be effective in May 2009 was published in the Federal Register (74 FR 15380–15384) on April 6, 2009. The final rule included new deflection standards, previously applicable only to automation flats, for all commercial flat-size mail except saturation and high-density Periodicals and Standard Mail® flats, as a basic