the Type C medicated feeds of 75 to 125 percent of the labeled amount. The assay limits for the halofuginone Type A medicated articles of 90 to 115 percent of the labeled amount in the approved NADA were not published at that time.

In the Federal Register of March 3, 1986 (51 FR 7382 at 7393), FDA added § 558.4 (21 CFR 558.4) providing for the regulation of medicated feed applications. In § 558.4, FDA incorrectly published the assay limits for Type A medicated articles of 80 to 120 percent of the labeled amount. At this time, FDA is amending the assay limits for Type A medicated articles to reflect those levels in the approved application. Accordingly, FDA is correcting § 558.4(d) to provide for an assay limit for halofuginone hydrobromide Type A medicated articles of 90 to 115 percent of the labeled amount instead of 80 to 120 percent.

List of Subjects in 21 CFR Part 558

Animals, Animal drugs, Animal feeds. 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 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:


§ 558.4 [Amended]

2. Section 558.4 Medicated feed applications is amended in paragraph (d), in the table entitled “Category II”, in the entry “Halofuginone hydrobromide” in the second column by removing “80–120” and adding in its place “90–115”.


Steven D. Vaughn,
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline, Sulfathiazole, Penicillin; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the Federal Register on January 15, 1998 (63 FR 2306). The document amended the animal drug regulations to reflect approval of Hoffmann-La Roche, Inc.’s, abbreviated new animal drug regulation (ANADA), ANADA 200–167 provides for use of Aureozol®, a Type A medicated article containing chlortetracycline, sulfathiazole, and penicillin to make Type C medicated swine feeds.


For further information contact: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 15, 1998 (63 FR 2306), FDA published a document reflecting approval of Hoffman-La Roche, Inc.’s, ANADA 200–167. The approval was for Aureozol®, a Type A medicated article containing chlortetracycline calcium complex equivalent to 40 grams (g) of chlortetracycline hydrochloride, 8.8 percent (40 g) sulfathiazole, and procaine penicillin equivalent in activity to 20 g of penicillin per pound, to make Type C medicated swine feeds containing 100 g of chlortetracycline, 100 g of sulfathiazole, and 50 g of penicillin per ton of feed. Hoffmann-La Roche’s ANADA 200–167 was approved as a generic copy of Boehringer Ingelheim Animal Health, Inc.’s, NADA 39–077 CSP 500 Fermazole Brand (chlortetracycline (as hydrochloride), sulfathiazole, penicillin (from procaine penicillin)).

The regulations that were amended in § 558.155(a)(2) to reflect the approval provided the incorrect drug labeler number. This document corrects the error by providing for “Nos. 000004 and 000010.”

In FR Doc. 98–703, appearing on page 2306 in the Federal Register of Thursday, January 15, 1998, the following correction is made:

§ 558.155 [Corrected]

1. On page 2307, in the second column, amendment no. 2 is corrected to read “Section 558.155 Chlortetracycline, sulfathiazole, penicillin is amended in paragraph (a)(2) by removing ‘000010’ and adding in its place ‘Nos. 000004 and 000010’.”