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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is updating the animal drug regulations to add Triple "F", Inc., to the list of sponsors of approved animal drug applications, and to add the drug labeler code (DLC) number for ADM Animal Health & Nutrition Division (ADM) to the list of approvals for bambermycins. These corrections amend the animal drug regulations to reflect currently approved new animal drug applications (NADA's).

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

FOR FURTHER INFORMATION CONTACT: Judith M. O'Haro, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-3664.

SUPPLEMENTARY INFORMATION: FDA has found that the April 1, 2000, edition of Title 21, Parts 500 to 599 of the *Code of Federal Regulations* (CFR) does not fully reflect several approved NADA's. Triple "F", Inc., is the holder of approved new animal drug applications (NADA's). The former DLC number for Triple "F", Inc., 011490, is listed in the regulation for bambermycins in § 558.95 (21 CFR 558.95) and for pyrantel tartrate in 21 CFR 558.485, but the sponsor and DLC are not listed under sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)). In a document published in the **Federal Register** of April 1, 1999 (64 FR 15683), the listing for Triple "F," Inc., was inadvertently deleted from § 510.600(c). ADM is a holder of approved NADA 132-448 for the use of bambermycins, but is not listed in the bambermycins regulations

(§ 558.95) by its current DLC. ADM is listed in § 558.95(a)(4) by its former DLC, 012286. This DLC was changed to 017519 in the **Federal Register** of May 21, 1997 (62 FR 27691), but the change was not reflected in § 558.95. At this time, FDA is amending the regulations to correct these errors in §§ 510.600(c) and 558.95(a).

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 558 are amended as follows:

PART—510 NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by adding alphabetically an entry for “Triple ‘F’,” Inc.” and in the table in paragraph (c)(2) by adding numerically an entry for “011490” 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
* * * * * Triple "F", Inc., 10104 Douglas Ave., Des Moines, IA 50322	* * * * * 011490

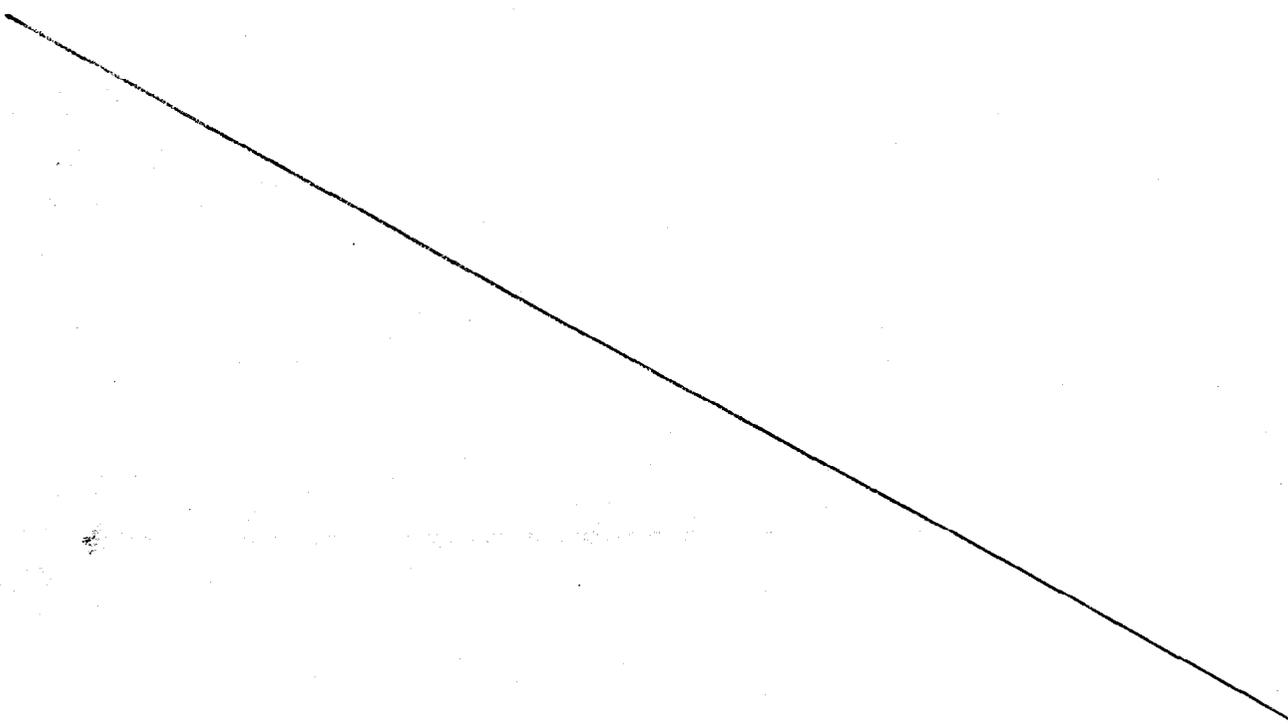
(2) * * *

Drug labeler code	Firm name and address
* * * * * 011490	* * * * * Triple "F", Inc., 10104 Douglas Ave., Des Moines, IA 50322

PART—558 NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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



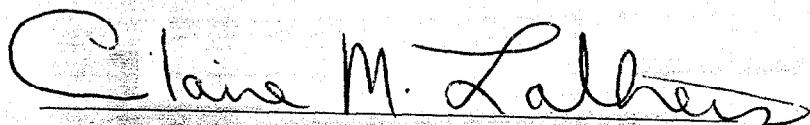
§ 558.95 [Amended]

4. Section 558.95 *Bambermycins* is amended in paragraph (a)(4) by removing "012286" and by numerically adding "017519,".

Dated: _____

8/23/00

August 23, 2000



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

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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