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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 September 7, 2000.

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: August 23, 2000.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
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DEPARTMENT OF STATE**22 CFR Part 22**

[Public Notice 3407]

Schedule of Fees for Consular Services, Department of State and Overseas Embassies and Consulates

AGENCY: Bureau of Consular Affairs.

ACTION: Final rule.

SUMMARY: This final rule amends the Schedule of Fees for Consular Services. Specifically, it establishes a fee for the review of the Affidavit of Support (Form I–864), when submitted in support of an application for immigration to the United States.

DATES: The effective date for the new AOS fee is October 1, 2000. I–864 forms sent to petitioners by the National Visa Center (NVC) or by posts overseas after October 1, 2000, will be subject to the new AOS fee as stated below.

ADDRESSES: Office of the Executive Director, Bureau of Consular Affairs, Department of State, SA–1, 10th Floor, 2401 E Street, NW., Washington, DC 20522–0111; telefax (202) 663–2499.

FOR FURTHER INFORMATION CONTACT: Alcy Frelick, Office of the Executive Director, Bureau of Consular Affairs, Department of State, SA–1, 10th Floor, 2401 E Street, NW., Washington, DC 20522–0111; telefax (202) 663–2499; email address frelickar@state.gov.

SUPPLEMENTARY INFORMATION: The amendment to the Schedule of Fees was published as a proposed rule on March 13, 2000 (65 FR 13253–13254). During the 30-day public comment period, three written comments were received from the general public. Those comments are addressed below. For the reasons explained, the Department is setting the Affidavit of Support fee

(AOS fee) at \$50.00 as originally proposed, but will be making a change to the effective date of the rule to address concerns raised by the commenters.

The public comments received by the Department focused on two aspects of the proposed new AOS fee: (1) That only one AOS fee should be charged per immigrant visa case (*i.e.* for all I–864 forms submitted in connection with an immigrant visa case comprised of a principal applicant and his/her eligible dependents) and (2) that the new AOS fee should not be charged until service to potential immigrants and their sponsors improves. The Department's response to the comments received is described below.

Only a single fee per family should be charged: The Department received comments from two sources expressing concern about the proposal to charge the AOS fee for each I–864 form submitted in support of an immigration case. The commenters argue that in cases where multiple I–864 forms are required in order to overcome the public charge provision, only one AOS fee should be charged.

Because the revenue from this fee is to be used to recover the costs of providing assistance to sponsors, co-sponsors and joint sponsors completing the I–864 form in support of an application for immigration to the United States, the Department cannot concur in this recommendation. One AOS fee will be charged for each I–864 form filed by the sponsor/petitioner, but no additional fee will be charged for an I–864a form filed by a co-sponsor. However, an additional AOS fee will be assessed for each I–864 form filed by any joint sponsor, as each individual submitting the I–864 form could potentially require assistance in completing the form. The services will be available to any party requiring assistance regardless of whether the person is a primary or a joint sponsor. It should also be noted that no additional AOS fee will be assessed when essentially duplicative I–864 forms are submitted on behalf of beneficiaries of separate petitions (for example, for parents of a US citizen for whom separate petitions must be filed).

The Department initially proposed imposing a separate AOS fee for the primary and each joint I–864 form submitted on behalf of an immigrant visa applicant because each I–864 form must be reviewed separately for technical completeness and assessed separately when evaluating the applicant's eligibility vis-a-vis the public charge provision. The Department has reviewed this proposal

in light of comments received and decided that averaging the costs of evaluating all I–864 forms into a single, uniform AOS fee per immigrant visa case would not be equitable for all applicants. Establishing a single AOS fee for an immigrant visa case would necessitate setting a higher fee to recover all the costs of the services provided and hence would result in all primary sponsors subsidizing a limited number of joint sponsors. Requiring payment of the AOS fee for each I–864 form submitted will also simplify the Department's fee collection procedures, thus reducing administrative costs.

The fee should be assessed only after service improves: One commenter took the view that the proposed fee would simply present another impediment in the process and would not result in improved service to potential applicants. However, the Department has already undertaken to improve service to applicants, and the revenue from the AOS fee will enable the Department to expand those services and to add additional ones.

In December 1998, the National Visa Center (NVC) established a pilot program (the AOS review program) to review the I–864 forms submitted for applicants applying at three posts—Ciudad Juarez, Manila and Santo Domingo. The Department undertook this review process to ensure that all I–864 forms sent to the pilot posts would be technically correct (the signatures properly notarized, the form completed, and all relevant supporting documentation attached). While the start-up period involved some delays, the process is now in place and functioning smoothly. The results of the pilot project have been positive with reduced refusal rates for the pilot posts. The I–864 forms submitted in support of immigrant visa applications at those posts are now technically more complete than previously, resulting in a reduced number of repeat interviews.

The AOS review program at NVC has recently been expanded to review I–864 forms submitted for immigrants processed at 10 posts. These ten posts (Manila, Ciudad Juarez, Santo Domingo, Guangzhou, Bogota, Port au Prince, Georgetown, Freetown, Tirana and Montreal) represent approximately 40% of the worldwide immigrant visa caseload. The I–864 forms for these posts are now being reviewed for technical completeness at NVC before the files go overseas. It is anticipated that the AOS review program at NVC will continue to expand until all I–864 forms submitted to posts overseas are reviewed for technical completeness prior to being sent to posts.