

unable to submit any filings during that time). * * *

Execution

* * * I understand that if any information contained in items 1D or 1E of this Form ADV-W is different from the information contained on Form ADV, the information on this Form ADV-W will replace the corresponding entry on the adviser's Form ADV composite available through IARD.
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■ 9. Form ADV-H (referenced in § 279.3) is amended by revising the phrase "Item 12 of Form ADV" in the third and fourth unnumbered paragraphs in Item 1B. to read "Item 12 of Part 1A of Form ADV".

Note: Form ADV-H does not and this amendment will not appear in the Code of Federal Regulations.

Dated: July 11, 2003.

By the Commission.

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 03-18122 Filed 7-16-03; 8:45 am]

BILLING CODE 8010-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

New Animal Drugs; Change of Sponsor; 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** of June 4, 2003 (68 FR 33381). The document amended the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Combe, Inc., to Farnam Companies, Inc. The document was published with some errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 03-14107, appearing on page 33381 in the **Federal Register** of June 4, 2003, the following corrections are made:

■ 1. On page 33381, in the first column, in the "SUMMARY", the word "Farnham" is corrected to read "Farnam".

■ 2. On page 33381, in the second column, in the sixth line from the bottom, "\$ 524.1580b [Amended]" is corrected to read "\$ 524.1376 [Amended]".

Dated: July 7, 2003.

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
[FR Doc. 03-18086 Filed 7-16-03; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol

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 abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental ANADA provides for the addition of tylosin tartrate to an approved subcutaneous implant containing trenbolone and estradiol used for increased rate of weight gain and improved feed efficiency in feedlot heifers.

DATES: This rule is effective July 17, 2003.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; 301-827-0232; edubbin@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200-346 for COMPONENT TE-H (trenbolone acetate and estradiol), a subcutaneous implant used for increased rate of weight gain and improved feed efficiency in heifers fed in confinement for slaughter. The supplemental ANADA provides for the addition of a pellet containing 29 milligrams tylosin tartrate to the approved implant. The supplemental application is approved as of April 18, 2003, and the regulations are amended

in 21 CFR 522.2477 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning April 18, 2003.

The agency has determined under 21 CFR 25.33(a)(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 522

Animal drugs.

■ 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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Section 522.2477 is amended in paragraph (b)(1) by adding "(d)(2)(i)(B)," after "(d)(2)(i)(A)," in paragraph (b)(2) by removing "(d)(2)" and by adding in its place "(d)(2)(i)(A), (d)(2)(i)(C), (d)(2)(i)(D), (d)(2)(ii), (d)(2)(iii)"; in paragraph (d)(2)(i)(A) by removing "paragraphs (d)(2)(ii)(A) and (d)(2)(ii)(B)" and by adding in its place "paragraph (d)(2)(ii)(A)"; by redesignating paragraphs (d)(2)(i)(B) and (d)(2)(i)(C) as paragraphs (d)(2)(i)(C) and (d)(2)(i)(D); and by adding new paragraph (d)(2)(i)(B) to read as follows: