

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

9938 '01 NOV -5 A11 :28

DMB

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Certifier	SKEESE

Implantation or Injectable Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Elanco Animal Health, A Division of Eli Lilly & Co., to Ivy Laboratories, Div. of Ivy Animal Health, Inc.

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

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: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, has informed FDA that it has transferred **to** Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park; KS 66214, ownership of, and all rights and interests in NADA 118-123 for COMPUDOSE 200 (estradiol) and COMPUDOSE 400 implants for cattle. Accordingly, the agency is amending the regulations in 21 CFR 522.840 to reflect the transfer of ownership.

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.

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NFR1

List of Subjects in 21 CFR Part 522

Animal drugs.

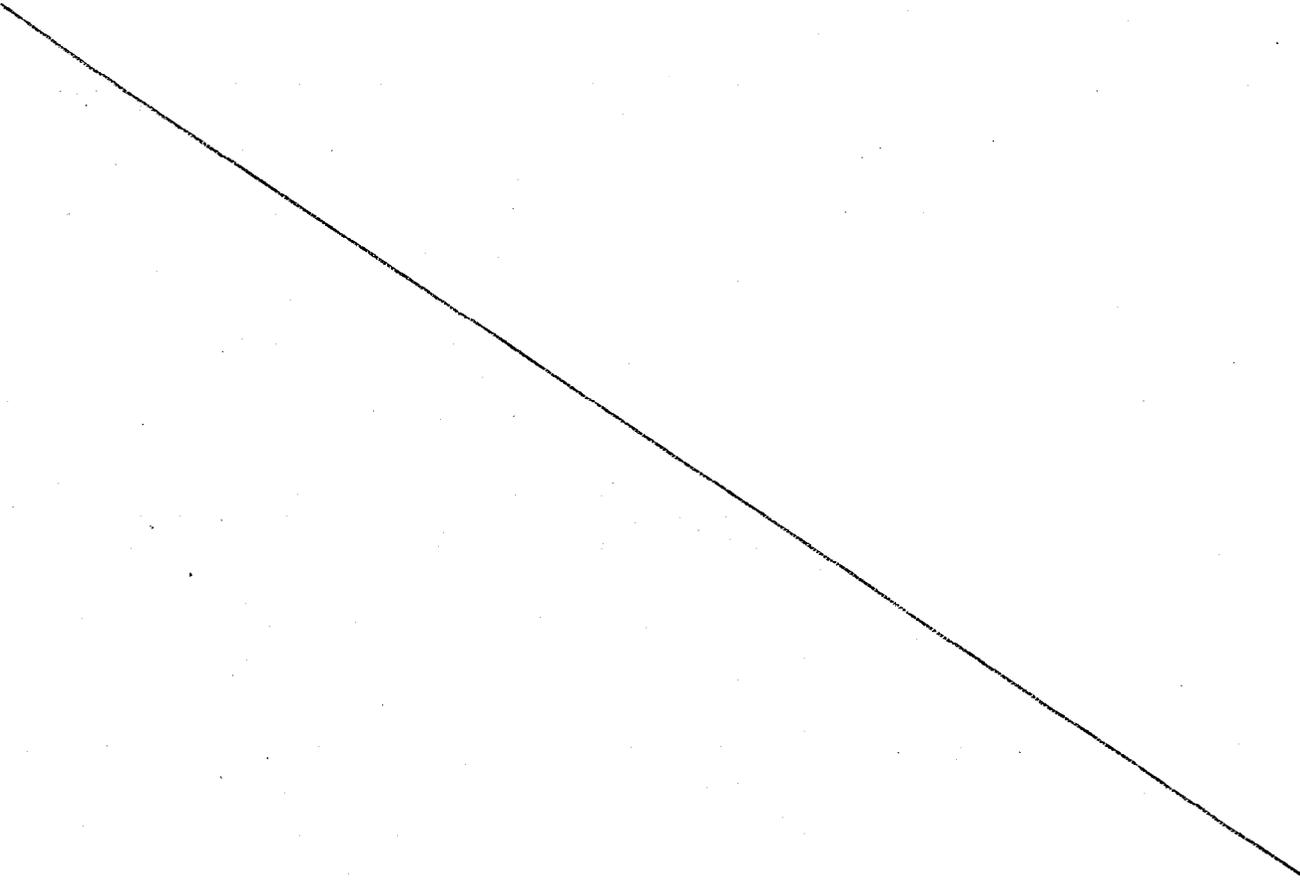
Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

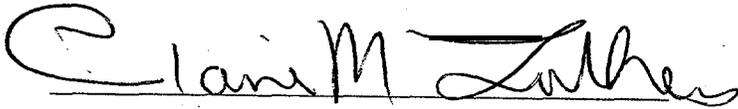
Authority: 21 U.S.C. 360b.

§ 522.840 [Amended]



2. Section 522.840 *Estradiol* is amended in paragraph (b) by removing "000986" and by adding in its place "No. 021641".

Dated: 10/26/01
October 26, 2001.



Claire M. Lathers,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.
[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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