

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

DDME  
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Certifier Shane

**Implantation or Injectable Dosage Form New Animal Drugs; Cloprostenol Sodium**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Parnell Laboratories (Aust) Pty. Ltd. The ANADA provides for the veterinary prescription use of cloprostenol sodium injectable solution in cattle for manipulation of the estrous cycle.

**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-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: [lluther@cvm.fda.gov](mailto:lluther@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Parnell Laboratories (Aust) Pty. Ltd., Century Estate, unit 6, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia, filed ANADA 200-310 for the use of ESTROPLAN (cloprostenol sodium) Injection by veterinary prescription for manipulation of the estrous cycle of cattle. Parnell Laboratories (Aust) Pty. Ltd.'s ESTROPLAN Injection is approved as a generic copy of Schering-Plough Animal Health Corp.'s ESTRUMATE, approved under NADA 113-645. The ANADA is approved as of May 13, 2004, and the regulations are amended in 21 CFR 522.460 to reflect

the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Parnell Laboratories (Aust) Pty. Ltd., is not currently listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

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 Division of Dockets Management (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.

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**

#### *21 CFR Part 510*

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

#### *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 parts 510 and 522 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 alphabetically adding an entry for “Parnell Laboratories (Aust) Pty. Ltd.”; and in the table in paragraph (c)(2) by numerically adding an entry for “068504” 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
* * * * *	
Parnell Laboratories (Aust) Pty. Ltd., Century Estate, unit 6, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia	068504

(2) \* \* \*

Drug labeler code	Firm name and address
* * * * *	
068504	Parnell Laboratories (Aust) Pty. Ltd., Century Estate, unit 6, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia

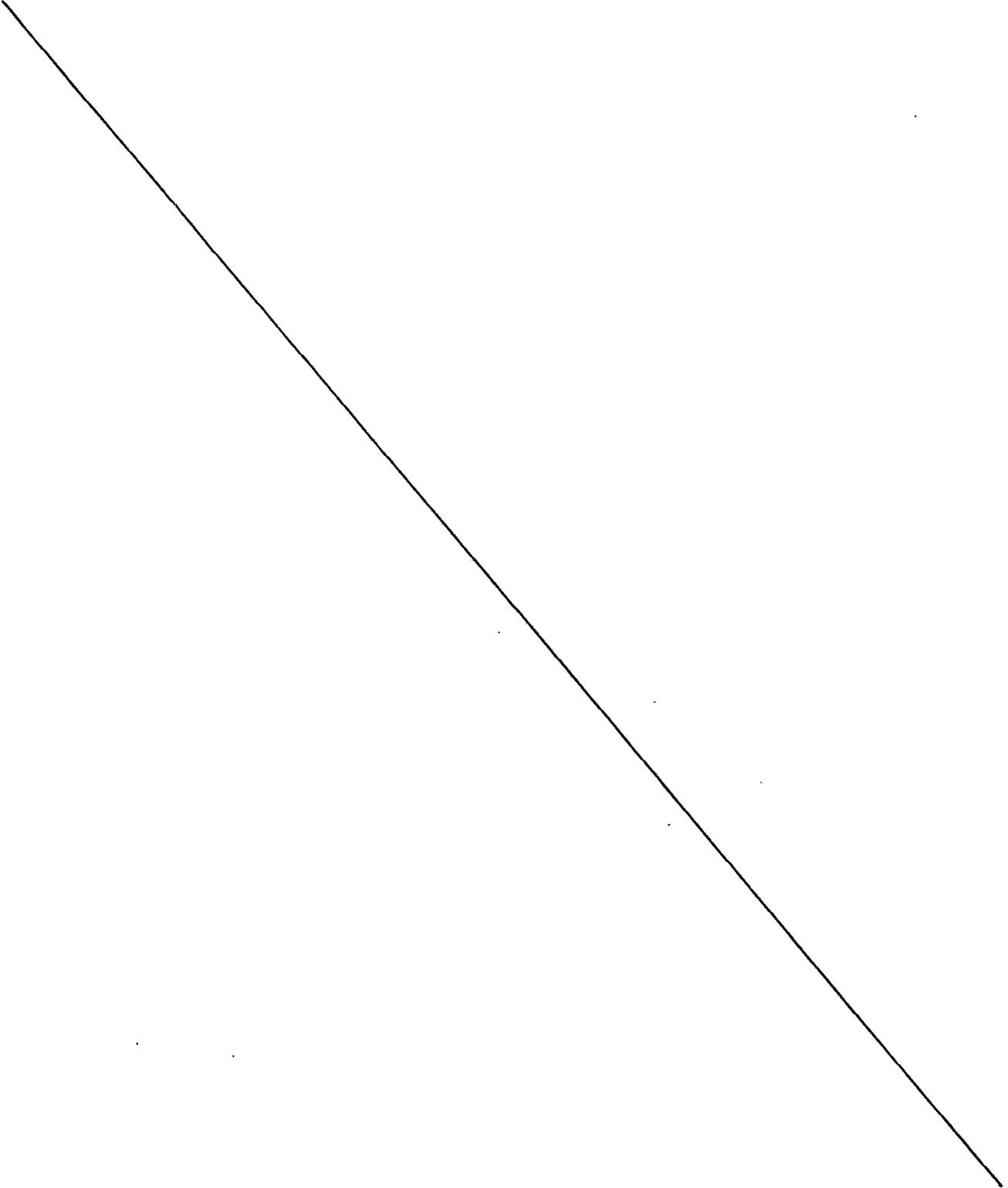
**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

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

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

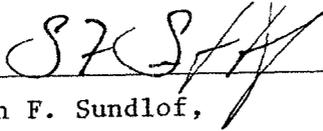
**§ 522.460 [Amended]**

■ 4. Section 522.460 is amended in paragraph (a)(2) by removing “No. 000061” and by adding in its place “Nos. 000061 and 068504”.



Dated: 6/17/04

June 17, 2004.



Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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