

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

#### Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

#### PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

■ 2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

#### 2004-13-26 Kaman Aerospace

**Corporation:** Amendment 39-13708.  
Docket No. 2003-SW-46-AD.

**Applicability:** Model K-1200 helicopters, certificated in any category.

**Compliance:** Required as indicated.

To prevent failure of a blade grip, blade contact with the opposite rotor mast, blade failure, and loss of control of the helicopter, accomplish the following:

(a) Before further flight, unless accomplished previously, remove the paint topcoat and primer from each blade grip; and using a light and 10x power or higher magnifying glass, visually inspect each blade

grip in accordance with the Accomplishment Instructions, paragraph 1. and 2.a., of Kaman Aerospace Corporation Service Bulletin No. 109, dated October 31, 2003 (SB).

**Note:** Do not damage or remove the sealant around the blade grip bolt heads and nuts.

(1) If a crack is detected, remove the grip and replace it with an airworthy grip.

(2) If no crack is detected, cover the exposed area with corrosion preventative compound.

(b) Before the first flight of each day, remove corrosion preventative compound from each blade grip using acetone. Using a light and 10x power or higher magnifying glass, visually inspect each blade grip for a crack in the area depicted in Figure 1 of the SB.

(1) If a crack is detected, remove the grip and replace it with an airworthy grip.

(2) If no crack is detected, cover the exposed area with corrosive preventative compound.

(c) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Safety Management Group, Rotorcraft Directorate, FAA, for information about previously approved alternative methods of compliance.

(d) Special flight permits will not be issued.

(e) The inspections shall be done in accordance with Kaman Aerospace Corporation Service Bulletin No. 109, dated October 31, 2003. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Kaman Aerospace Corporation, P.O. Box 2, Old Windsor Rd., Bloomfield, CT 06002-0002, telephone (888) 626-KMAX (5629), fax (880) 243-7047. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(f) This amendment becomes effective on July 22, 2004.

Issued in Fort Worth, Texas, on June 24, 2004.

**Kim Smith,**

*Acting Manager, Rotorcraft Directorate,  
Aircraft Certification Service.*

[FR Doc. 04-15127 Filed 7-6-04; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 172

[Docket No. 1999F-0719]

#### Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra; 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 May 24, 2004 (69 FR 29428). The final rule amended the food additive regulations to allow for the safe use of olestra as a replacement for fats and oils in prepackaged, unpopped popcorn kernels that are ready-to-heat. The initial action was in response to a food additive petition (FAP) filed by the Procter and Gamble Co. The final rule published with an inadvertent error. This document corrects that error.

**EFFECTIVE DATE:** July 7, 2004.

**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. 04-11502, appearing on page 29428 in the **Federal Register** of May 24, 2004, the following correction is made:

1. On page 29429, under **SUPPLEMENTARY INFORMATION**, in the second column, in the first line of the first complete paragraph, the phrase "noted in the FAP" is corrected to read "noted in the notice of filing".

Dated: July 1, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-15424 Filed 7-6-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 510 and 522

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

**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 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 July 7, 2004.

**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: June 17, 2004.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 04-15425 Filed 7-6-04; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 524**

**Ophthalmic and Topical Dosage Form New Animal Drugs; Diclofenac**

**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 new animal drug application (NADA) filed by IDEXX Pharmaceuticals, Inc. The NADA provides for topical use of diclofenac cream in horses for the control of pain and inflammation associated with osteoarthritis in tarsal, carpal, metacarpophalangeal, metatarsophalangeal, and proximal interphalangeal (hock, knee, fetlock, and pastern) joints.

**DATES:** This rule is effective July 7, 2004.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543, e-mail: [mberson@cvm.fda.gov](mailto:mberson@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** IDEXX Pharmaceuticals, Inc., 4249-105 Piedmont Pkwy., Greensboro, NC 27410, filed NADA 141-186 that provides for use of SURPASS (1 % diclofenac sodium) Topical Cream in horses for the control of pain and inflammation associated with osteoarthritis in tarsal, carpal, metacarpophalangeal, metatarsophalangeal, and proximal interphalangeal (hock, knee, fetlock and pastern) joints. The NADA is approved