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*.

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*.

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

as of May 13, 2004, and the regulations are amended in 21 CFR part 524 by adding § 524.590 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 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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning May 13, 2004.

The agency has determined under 21 CFR 25.33(d)(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 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 2. Section 524.590 is added to read as follows:

§ 524.590 Diclofenac.

(a) *Specifications.* Each gram of cream contains 10 milligrams diclofenac sodium.

(b) *Sponsor.* See No. 065274 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Apply a 5-inch (5″) ribbon of cream twice daily over the affected joint for up to 10 days and rub thoroughly into the hair covering the joint until it disappears.

(2) *Indications for use 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.

(3) *Limitations.* Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: June 17, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04–15426 Filed 7–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 151

[USCG–2002–13147]

RIN 1625–AA51

Penalties for Non-Submission of Ballast Water Management Reports

AGENCY: Coast Guard, DHS.

ACTION: Final rule; correction.

SUMMARY: The Coast Guard is correcting a final rule that appeared in the **Federal Register** of June 14, 2004 (69 FR 32864). The final rule changes regulations for vessels equipped with ballast water tanks bound for ports or places within the United States. These corrections clarify the final rule.

DATES: This correction is effective on June 14, 2004.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Mr. Bivan Patnaik, Project Manager, Environmental Standards Division, Coast Guard, telephone 202–267–1744, e-mail: *bpatnaik@comdt.uscg.mil.* If you have questions on viewing the docket, call Ms. Andrea M. Jenkins, Program Manager, Docket Operations, telephone 202–366–0271.

SUPPLEMENTARY INFORMATION: In FR Doc. 04–13173 appearing on page 32864 of the **Federal Register** of Monday, June 14, 2004, the following corrections are made:

■ 1. On page 32865, the paragraph beginning at the end of the second column and continuing in the third column is corrected to read as follows:

''Although, the penalty amount of $25,000 was discussed in the notice of proposed rulemaking, the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, requires the Coast Guard to adjust penalties for violating Federal laws set by Congress long ago where the deterrent value of the penalties have weakened with time due to inflation. As such, we have changed the monetary amount authorized by NISA, from $25,000 to $27,500. With respect to the commenters' concern about the penalty amount, we believe there is some confusion. The penalty is not $27,500; rather, the penalty is not to exceed $27,500. We have the discretion to issue a penalty of up to $27,500, depending on the facts of each individual case.''

■ 2. On page 32866, the first paragraph of the third column, remove the three asterisks in the first sentence.

■ 3. On page 32867, in the second full paragraph of the second column, remove the word ''COPT'' and in its place, add the word ''COTP''.

■ 4. To clarify the Coast Guard's response to comments submitted in the Comments on Definitions section on page 32867, the second paragraph of the third column is corrected as follows:

The Coast Guard disagrees with this comment. ''Ports and places'' are defined in § 151.2025 and are defined in the exact way as in 33 CFR 160.204 of, ''Notification of Arrivals, Departures, Hazardous Conditions, and Certain Dangerous Cargoes.'' The Coast Guard must evaluate the BWM operations of all vessels operating within U.S. waters. Therefore, MODUs or OSVs servicing OCS facilities within the EEZ while moving from one COTP zone to another, must submit ballast water reporting forms. MODUs or OSVs servicing OCS facilities outside the EEZ will not be required to submit ballast water reporting forms, however, upon returning to ports or places of the U.S they will have to submit ballast water reporting forms. Regulatory language in § 151.2041 will be amended to reflect this clarification. If, after a period of time we determine that we are receiving data that does not benefit our evaluation, we will then revisit the program and adjust it accordingly.

■ 5. On page 32869, in the middle column, in amendatory instruction numbers 1 and 4, remove the word ''continues''.

§ 151.2041 [Amended]

■ 6. On page 32870, in the second column, correct the section heading for § 151.2041 and paragraph (a) by removing the phrase ''bound for ports or places in the United States'' and add in its place the phrase ''bound for ports or places of the United States''.