

the words "FAA Order 7400.9N" and adding, in their place, the words "FAA Order 7400.9P."

§ 71.901 [Amended]

■ 10. Paragraph (a) of section 71.901 is amended by removing the words "FAA Order 7400.9N" and adding, in their place, the words "FAA Order 7400.9P."

Issued in Washington, DC, on July 27, 2006.

Edith V. Parish,

Manager, Airspace and Rules.

[FR Doc. E6-12434 Filed 8-31-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Carprofen

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 IMPAX Laboratories, Inc. The supplemental ANADA provides for veterinary prescription use of carprofen caplets in dogs for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

DATES: This rule is effective September 1, 2006.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-9808, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544, filed a supplement to ANADA 200-366 for NOVOX (carprofen) caplets which are approved for veterinary prescription use in dogs for the relief of pain and inflammation associated with osteoarthritis (70 FR 30625, May 27, 2005). The supplement provides for use of NOVOX caplets for the control of postoperative pain associated with soft tissue and orthopedic surgeries. The supplemental ANADA is approved as of July 27, 2006, and 21 CFR 520.309 is amended to reflect the approval.

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 in 21 CFR Part 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. In § 520.309, remove paragraphs (d)(2)(i) and (d)(2)(ii), and revise paragraphs (b)(2) and (d)(2) to read as follows:

§ 520.309 Carprofen.

* * * * *

(b) * * *

(2) No. 000115 for use of product described in paragraph (a)(1) as in paragraph (d) of this section.

* * * * *

(d) * * *

(2) *Indications for use.* For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

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Dated: August 18, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. E6-14508 Filed 8-31-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Lincomycin

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 Cross Vetpharm Group Ltd. The ANADA provides for the use of lincomycin injectable solution in swine for the treatment of infectious arthritis and mycoplasma pneumonia.

DATES: This rule is effective September 1, 2006.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200-368 that provides for use of LINCOMED 100 (lincomycin hydrochloride) and LINCOMED 300 (lincomycin hydrochloride) in swine for the treatment of infectious arthritis and mycoplasma pneumonia. Cross Vetpharm Group Ltd.'s LINCOMED 100 and LINCOMED 300 are approved as generic copies of LINCOMIX 100 Injectable and LINCOMIX 300 Injectable, sponsored by Pharmacia & Upjohn Co., a Division of Pfizer, Inc., under NADA 034 025. The ANADA is approved as of July 27, 2006, and the regulations are amended in § 522.1260 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.

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