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]

BILLING CODE 4910–13–P

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.

* * * * *

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]

BILLING CODE 4160–01–S

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

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 Subject 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.

■ 2. In § 522.1260, add paragraphs (a)(4) and (b)(4) to read as follows:

§ 522.1260 Lincomycin.

(a) * * *

(4) 100 or 300 mg lincomycin.

(b) * * *

(4) No. 061623 for use of concentrations in paragraph (a)(4) of this section as in paragraph (e)(2) of this section.

* * * * *

Dated: August 10, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–14509 Filed 8–31–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–289I]

RIN 1117–AB04

Schedules of Controlled Substances: Exempt Anabolic Steroid Products

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Interim rule and request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) is designating six pharmaceutical preparations as exempt anabolic steroid products under the Controlled Substances Act. This action is part of the ongoing implementation of the Anabolic Steroids Control Act of 1990.

DATES: This rule is effective September 1, 2006. Written comments must be postmarked, and electronic comments must be sent, on or before October 31, 2006.

ADDRESSES: To ensure proper handling of comments, please reference Docket No. DEA–289 on all written and electronic correspondence. Written comments sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be sent electronically to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided at that site. DEA will accept attachments to electronic comments in Microsoft Word, Word Perfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Background

The Anabolic Steroids Control Act (ASCA) of 1990 (Title XIX of Pub. L. 101–647) placed anabolic steroids into Schedule III of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). Section 1903 of the ASCA provides that the Attorney General may exempt products which contain anabolic steroids from all or any part of the Controlled Substances Act if the products have no significant potential for abuse. The authority to exempt these products was delegated from the Attorney General to the Administrator of the Drug Enforcement Administration (28 CFR 0.100(b)), who in turn, redelegated this authority to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (28 CFR Part 0, Appendix to Subpart R, section 7(g)). The procedure for implementing this section of the ASCA is found in § 1308.33 of Title 21 of the Code of Federal Regulations. Three applications which were in conformance with 21 CFR 1308.33 were received and forwarded to the Secretary of Health and Human Services for evaluation. The purpose of this rule is to identify six products which the Deputy Assistant Administrator, Office of Diversion Control, finds meet the exempt anabolic steroid product criteria.

Anabolic Steroid Products Being Added to the List of Products Exempted From Application of the CSA

DEA received three letters dated June 8, 2005, July 1, 2005 and August 22, 2005, written to the DEA on behalf of Interpharm Inc., Lannett Company Inc., and ANDAPharm, LLC, respectively. Each of these three letters contained an application to exempt from control under the CSA two products, each containing esterified estrogens and methyltestosterone. In two letters dated November 14, 2005, DEA provided a copy of the Lannett and ANDAPharm applications to the Department of Health and Human Services (DHHS) along with a request for evaluation and a recommendation. In a letter dated November 15, 2005, DEA provided a copy of the Interpharm application to DHHS along with a request for evaluation and recommendation. In three separate letters dated March 30, 2006, the Assistant Secretary of Health for DHHS recommended that all six products, two products of esterified estrogen and methyltestosterone from each of the three applications, be exempted from control under the CSA based on their similarity to the products Estratest®, Estratest® H.S., Essian™ and Essian™ H.S., which have been exempted from control under the CSA.

DEA agrees with DHHS regarding the similarity of these products to products which have already been exempted from the regulatory controls of the Controlled Substances Act. Further, after reviewing several law enforcement databases, DEA has not found evidence of significant abuse or trafficking of these types of products.

The Deputy Assistant Administrator, having reviewed the applications, recommendations of the Secretary, and other relevant information, finds that the following six products have no significant potential for abuse: Esterified Estrogens and Methyltestosterone, USP (1.25 mg/2.5 mg); Esterified Estrogens and Methyltestosterone, USP (0.625 mg/1.25 mg); Methyltestosterone and Esterified Estrogens (2.5 mg/1.25 mg); Methyltestosterone and Esterified