

the Commission to "consider the costs and benefits" of its action.

Section 15(a) further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: Protection of market participants and the public; efficiency, competitiveness, and financial integrity of futures markets; price discovery; sound risk management practices; and other public interest considerations. Accordingly, the Commission could in its discretion give greater weight to any one of the five enumerated areas and could in its discretion determine that, notwithstanding its costs, a particular rule was necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the Act.

The Commission is considering the costs and benefits of these rules in light of the specific provisions of Section 15(a) of the Act:

1. Protection of Market Participants and the Public

The amendments being adopted herein are not expected to result in less protection of market participants or the public. Rather, the amendments provide the opportunity for a more meaningful and accurate disclosure, as demanded by marketplace forces. Moreover, the Commission, along with NFA, will continue to monitor the presentation of performance by CTAs and take action wherever necessary.

2. Efficiency and Competition

The amendments are expected to increase efficiency by providing a CTA with increased flexibility for providing past performance. With this flexibility, a CTA will be better able to respond to changes in the industry and demands from the marketplace with regard to the disclosure of the CTA's past performance.

3. Financial Integrity of Futures Markets and Price Discovery

The amendments should have no effect, from the standpoint of imposing costs or creating benefits, on the financial integrity or price discovery function of the commodity futures and options markets.

4. Sound Risk Management Practices

The amendments should have no effect on sound risk management practices.

5. Other Public Interest Considerations

The amendments being adopted herein provide more flexibility for CTAs in being able to present past

performance in a manner that more accurately represents the trading results of their systems, while maintaining adequate safeguards so as to protect prospective clients from misleading or fraudulent solicitations.

After considering these factors, the Commission has determined to issue the amended rules.

List of Subjects in 17 CFR Part 4

Advertising, Commodity Futures, Customer Protection, Reporting and recordkeeping.

■ For the reasons discussed in the foregoing, the Commission hereby amends Chapter I of Title 17 of the Code of Federal Regulations as follows:

PART 4—COMMODITY POOL OPERATORS AND COMMODITY TRADING ADVISORS

■ 1. The authority citation for Part 4 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 6(c), 6b, 6c, 6l, 6m, 6n, 6o, 12a and 23.

■ 2. Section 4.10 is amended by adding paragraph (m) to read as follows:

§ 4.10 Definitions.

* * * * *

(m) *Partially-funded account* means a client participation in the program of a commodity trading advisor in which the amount of funds in the client's commodity interest account over which such commodity trading advisor has trading authority is less than the account size that establishes the client's level of trading in a commodity trading advisor's program.

■ 3. Section 4.25 is amended by adding paragraph (a)(1)(ii)(H) to read as follows:

§ 4.25 Performance disclosures.

* * * * *

(a) * * *

(1) * * *

(ii) * * *

(H) *Partially-funded accounts* directed by a commodity trading advisor may be presented in accordance with § 4.35(a)(7).

* * * * *

■ 4. Section 4.35 is amended as follows:

■ a. By redesignating paragraphs (a)(7) and (a)(8) as (a)(8) and (a)(9) respectively;

■ b. And adding new paragraph (a)(7) to read as follows:

§ 4.35 Performance disclosures.

* * * * *

(a)(7) *Performance of partially-funded accounts.* Notwithstanding the foregoing, a commodity trading advisor will be deemed in compliance with this § 4.35(a) concerning the performance of partially-funded accounts if the

commodity trading advisor presents the performance of such accounts in a manner that is balanced and is not in violation of the antifraud provisions of the Commodity Exchange Act or the Commission's regulations thereunder.

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Issued in Washington, DC, on July 15, 2003 by the Commission.

Jean A. Webb,

Secretary of the Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Meloxicam

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 Boehringer Ingelheim Vetmedica, Inc. The NADA provides for use of meloxicam oral suspension for the control of pain and inflammation associated with osteoarthritis in dogs.

DATES: This rule is effective July 21, 2003.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002, filed NADA 141-213 that provides for use of METACAM (meloxicam) Oral Suspension for the control of pain and inflammation associated with osteoarthritis in dogs. The NADA is approved as of April 15, 2003, and the regulations are amended in 21 CFR part 520 by adding new § 520.1350 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 part 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 Dockets Management

Branch (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 (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning April 15, 2003.

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 520

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 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. Section 520.1350 is added to read as follows:

§ 520.1350 Meloxicam.

(a) *Specifications.* Each milliliter of suspension contains 0.5 or 1.5 milligrams (mg) meloxicam.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (c) of this section.

(c) *Conditions of use in dogs—(1) Amount.* Administer orally 0.2 mg/kilogram (kg) body weight on the first day of treatment. For all treatment after day 1, administer 0.1 mg/kg body weight once daily.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: July 8, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03-18354 Filed 7-18-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder

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 Cross Vetpharm Group Ltd. The supplemental ANADA provides for a new pouch size of oxytetracycline hydrochloride soluble powder used to make medicated drinking water for swine.

DATES: This rule is effective July 21, 2003.

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: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed a supplement to ANADA 200-144 that provides for a new pouch size of TETROXY (oxytetracycline HCl) Soluble Powder used to make medicated drinking water for administration to swine. The supplemental application is approved as of April 21, 2003, and the regulations are amended in 21 CFR 520.1660d 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 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.

§ 520.1660d [Amended]

■ 2. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraph (a)(9) by removing "and 19.75 oz" and by adding in its place " , 19.75 oz, and 3.91 lb".

Dated: July 8, 2003.

Steven D. Vaughn,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Injectable or Implantable Dosage Form New Animal Drugs; Euthanasia Solution; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. and a supplemental abbreviated new animal drug application (ANADA) filed by Delmarva Laboratories, Inc. The supplemental applications add environmental warning statements to product labeling.

DATES: This rule is effective July 21, 2003.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7500 Standish