factors which, individually or in combination, indicate that a decline in value of an equity security classified as available-for-sale is other than temporary and that a write-down of the carrying value is required:

a. The length of the time and the extent to which the market value has been less than cost;

b. The financial condition and near-term prospects of the issuer, including any specific events which may influence the operations of the issuer such as changes in technology that may impair the earnings potential of the investment or the discontinuance of a segment of the business that may affect the future earnings potential; or

c. The intent and ability of the holder to retain its investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

Unless evidence exists to support a realizable value equal to or greater than the carrying value of the investment in equity securities classified as available-for-sale, a write-down to fair value accounted for as a realized loss should be recorded. Such loss should be recognized in the determination of net income of the period in which it occurs and the written down value of the investment in the company becomes the new cost basis of the investment.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2009–N–0665]

Oral Dosage Form New Animal Drugs; Fenbendazole Suspension

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 new animal drug application (NADA) filed by Intervet, Inc. The supplemental NADA provides for a revised human food safety warning for use of fenbendazole suspension in horses.

DATES: This rule is effective April 17, 2009.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8337, e-mail: *melanie.berson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed a supplement to NADA 104–494 that provides for use of PANACUR (fenbendazole) Suspension 10% in horses for the control of various internal parasites. The supplemental NADA provides for a revised human food safety warning on product labeling. The supplemental NADA is approved as of March 25, 2009, and the regulations are amended in 21 CFR 520.905a to reflect the approval and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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. Amend § 520.905a as follows:

■ a. Revise paragraph (a);

■ b. Remove paragraph (e);

■ c. Redesignate paragraph (d) as paragraph (e);

■ d. Add new paragraph (d); and

■ e. Revise newly redesignated paragraphs (e)(1)(i), (e)(1)(iii), (e)(2)(i), (e)(2)(iii), (e)(3)(i), (e)(3)(ii) , and (e)(4)(i).

The revisions and addition are to read as follows:

§ 520.905a Fenbendazole suspension.

(a) *Specifications.* Each milliliter of suspension contains 100 milligrams (mg) fenbendazole.

* * * * *

(d) *Special considerations*—(1) See § 500.25 of this chapter.

(2) Fenbendazole suspension 10 percent and approved forms of trichlorfon, when used concomitantly for treating the indications provided in paragraph (e) of this section and for treating infections of stomach bot as provided in § 520.2520, have been shown to be compatible and not to interfere with one another.

(e) * * *

(1) * * *

(i) *Amount.* Administer orally 5 mg per kilogram (/kg) (2.3 mg per pound (/lb)) for the control of large strongyles, small strongyles, and pinworms; 10 mg/kg for the control of ascarids.

* * * * *

(iii) *Limitations.* Administer by dose syringe or suitable plastic syringe. Do not use in horses intended for human consumption.

(2) * * *

(i) *Amount.* Administer orally 5 mg/kg of body weight (2.3 mg/lb).

* * * * *

(iii) *Limitations.* Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 8 days following last treatment.

(3) * * *

(i) *Amount.* Administer orally 10 mg/kg of body weight.

(ii) *Indications for use.* For the removal and control of stomach worm (4th stage inhibited larvae/type II ostertagiasis), *Ostertagia ostertagi*, and tapeworm, *Moniezia benedeni.*

* * * * *

(4) * * *

(i) *Amount.* Administer orally 5 mg/kg of body weight (2.3 mg/lb).

* * * * *

Dated: April 9, 2009.

Steven D. Vaughn,

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

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