■ 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. In § 510.600, in the table in paragraph (c)(1) remove the entry for ''Veterinary Research Associates, Inc.'' and alphabetically add a new entry for ''Putney, Inc.''; and in the table in paragraph (c)(2) remove the entry for ''064408'' and numerically add an entry for ''026637'' 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
* * * *	*
Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101	026637
* * * *	*

(2) * * *

Drug labeler code	Firm name and address
* * * *	*
026637	Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101
* * * *	*

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.

§ 522.1222a [Amended]

■ 4. In § 522.1222a, revise paragraph (b) by removing ''064408'' and numerically adding ''026637''.

Dated: January 31, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–2607 Filed 2–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Phenylbutazone Tablets

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 two supplemental new animal drug applications (NADAs) filed by IVX Animal Health, Inc. The supplemental NADAs provide revised labeling for phenylbutazone tablets used in horses and dogs.

DATES: This rule is effective February 13, 2008.

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: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed supplements to NADA 91–818 and NADA 94–170 for Phenylbutazone Tablets. The supplemental applications provide for revisions to warning statements on product labeling. The supplemental NADAs are approved as of January 17, 2008, and 21 CFR 520.1720a is amended to reflect the approval.

Approval of these supplemental NADAs 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 these actions are of a type that do 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. Revise § 520.1720a to read as follows:

§ 520.1720a Phenylbutazone tablets and boluses.

(a) *Specifications*. Each tablet contains 100, 200, or 400 milligrams (mg), or 1 gram (g) phenylbutazone. Each bolus contains 2 or 4 g phenylbutazone.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter, as follows:

(1) No. 000061 for use of 100- or 400-mg or 1-g tablets, or 2- or 4-g boluses, in dogs and horses.

(2) Nos. 000010 and 059130 for use of 100- or 200-mg or 1-g tablets in dogs and horses.

(3) Nos. 000856, 058829, and 061623 for use of 100-mg or 1-g tablets in dogs and horses.

(4) No. 055246 for use of 100-mg tablets in dogs.

(5) No. 000143 for use of 1-g tablets in horses.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 20 mg per pound of body weight daily.

(ii) *Indications for use*. For the relief of inflammatory conditions associated with the musculoskeletal system.

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

(2) *Horses*—(i) *Amount*. 1 to 2 g per 500 pounds of body weight daily.

(ii) *Indications for use*. For the relief of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: January 31, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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