

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

T.M.G. Display Date 7-9-03
Publication Date 7-10-03
Certifier R LEDESMA

Oral Dosage Form New Animal Drugs; Phenylbutazone Tablets and Boluses

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 West-Ward Pharmaceutical Corp. The ANADA provides for oral use of phenylbutazone tablets in horses for relief of inflammatory conditions associated with the musculoskeletal system.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

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: West-Ward Pharmaceutical Corp., 465 Industrial Way West, Eatontown, NJ 07724, filed ANADA 200-323 for the oral use of Phenylbutazone Tablets in horses for relief of inflammatory conditions associated with the musculoskeletal system. West-Ward Pharmaceutical's Phenylbutazone Tablets are approved as a generic copy of Boehringer Ingelheim Vetmedica's BIZOLIN (phenylbutazone) Tablets, approved under NADA 99-618. The ANADA is approved as of March 28, 2003, and the regulations are amended in 21 CFR 520.1720a to reflect the approval and

current format. The basis of approval is discussed in the freedom of information summary.

In addition, West-Ward Pharmaceutical Corp., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

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.

FDA 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 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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

4. Section 520.1720a is amended by adding paragraph (b)(5) to read as follows:

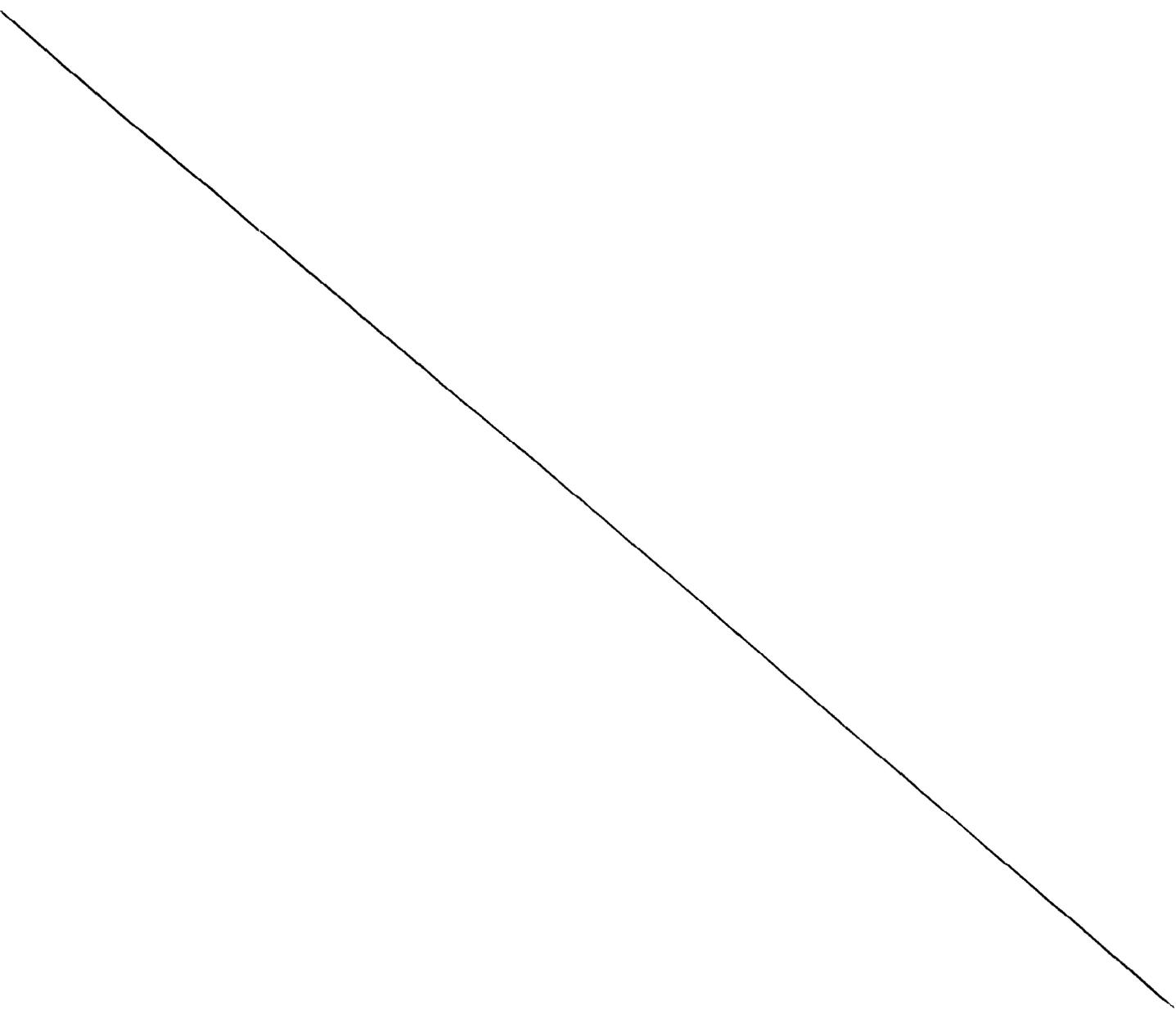
§ 520.1720a Phenylbutazone tablets and boluses.

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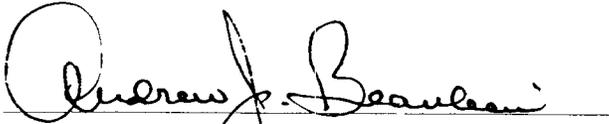
(b) * * *

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

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Dated: June 26, 2003
June 26, 2003.



Andrew J. Beaulieu,
Acting Director,
Center for Veterinary Medicine.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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