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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0039]

**Notice of Approval of Original Abbreviated New Animal Drug Application;
Phenylbutazone Tablets**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved an original abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for veterinary prescription use of phenylbutazone tablets in horses for the relief of inflammatory conditions associated with the musculoskeletal system.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200-433 providing for veterinary prescription use of Phenylbutazone Tablets in horses for the relief of inflammatory conditions associated with the musculoskeletal system. First Priority, Inc.'s, ANADA for Phenylbutazone Tablets is approved as a generic copy of First Priority, Inc.'s, PRIBUTAZONE Tablets, approved under NADA 48-647. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and part 514 (21 CFR part 514), in §§ 514.105(a) and 514.106(a), the Center

ANADA 200.433
FDA.2008.N.0039

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for Veterinary Medicine is providing notice that this ANADA is approved as of October 23, 2008.

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.

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.

Dated: November 5, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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