FIRST PRIORITY, INC.
Priority Care

March 1, 2001

Dockets Management Branch
HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION
(ANADA SUITABILITY PETITION)

First Priority, Inc hereby submits this petition under Section 512 (n) (3) of the Federal Food, Drug and Cosmetic Act to seek permission from the Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, to file an Abbreviated New Animal Drug Application(ANADA) which differs in dosage form from the innovator product.

A. Action requested

First Priority, Inc seeks permission to file an ANADA for a generic equivalent of the innovator product PHENYLBUTEB (phenybutazone tablets) , NADA 91-818, Phoenix Scientific, Inc. which differs from the innovator product in dosage form. Phenylbutazone generic is a palatable, chewable tablet whereas the pioneer product PHENYLBUTEB is a non-chewable oral tablet.

B. Statement of grounds

Under provisions of the Federal Food, Drug, and Cosmetic Act, Section 512 (n)

(3) If a person wants to submit an abbreviated application for a new animal drug-

(A) whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug, or
(B) whose use with other animal drugs in animal feed differs from that of an approved new animal drug,

such person shall submit a petition to the Secretary seeking permission to file such an application.

01P-0124 CP1

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This ANADA Suitability Petition qualifies under the provisions of the Federal Food, Drug, and Cosmetic Act, Section 512 (n) (3) (A) in that permission is sought to change only the dosage form of an approved new animal drug. Phenylbutazone genetic is a palatable, chewable tablet whereas PHENYLBUTEB (phenylbutazone tablets) is a non-chewable oral tablet,

The active ingredient in the phenylbutazone generic chewable, phenylbutazone, will be the same as the innovator PHENYLBUTE® (phenylbutazone tablets) and will be included in the genetic product at the same concentration and dosed at the same rate and frequency as the innovator:

A.	DOSAGE FORM	Phenylbutazone generic is formulated in a palatable, compressed chewable tablet. The dosage strength is 1 gram phenylbutazone per tablet.
B.	INDICATIONS	Phenylbutazone is for the relief of inflammatory conditions associated with the musculoskeletal system in horses.
C.	ROUTE OF ADMINISTRATION	The phenylbutazone generic chewable tablets are administered orally.
C.	RECOMMENDED DOSAGE	The phenylbutazone generic chewable tablets are administered orally 1 to 2 chewable tablets per 500 pounds of body weight, but not to exceed 4 g per animal daily. Use high dose for the first 48 hours, then gradually reduce to a maintenance dose.

The labeling for the phenylbutazone generic chewable tablet will be identical to the pioneer PHENYLBUTE® (phenylbutazone tablets) labeling with the exception of substitution of First Priority, Inc.'s product name(to be determined), company name, address and directions for administration of the palatable, chewable tablet versus the non-chewable oral tablet.

C. Environmental impact

First Priority, Inc believes that this petition is subject to categorical exclusion under 21 CFR 25.24.

D. Economic impact

An economic impact analysis will be provided if requested after review of this petition.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Lawrence Schneider, President
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