January 29, 2004

Document Control Unit (HFV-199)
Food and Drug Administration
Center for Veterinary Medicine
7500 Standish Place
Rockville, MD 20855

Re: Phenylbutazone Powder

Subject: Suitability Petition

Enclosed are four copies of a Suitability Petition submitted by Cross Vetpharm Group for Phenylbutazone Powder. Cross Vetpharm requests the Commissioner to permit the filing of a supplemental application for a proposed product that differs from the approved pioneer product Butatron (phenylbutazone) Tablets, sponsored by Cross Vetpharm Group, under NADA 044-756.

Permission is hereby requested to market a Phenylbutazone Powder that is the same formulation as the approved NADA Butatron (phenylbutazone) Tablets. We have included in this submission information to support our request.

Should you have any questions regarding this Suitability Petition, I can be reached at (515) 359-2248.

Sincerely,

Linda M. Duple

Linda M. Duple
Director, North American Regulatory Affairs

Enclosures

Cc: Phenylbutazone Powder INAD
Bimeda, Inc. – Le Sueur, MN
Bimeda, Inc. – Riverside, MO
Correspondence

2836 Dolliver Park Ave. • Lehigh, IA 50557
(515) 359-2248 • FAX (515) 359-2241 • www.bimeda.com

2004P-0058

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Cross Vetpharm Holdings Plc
Airton Road
Tallaght
Dublin 24
Ireland
Tel: (353) 1 4515522
Fax: (353) 1 4628860

CROSS VETPHARM HOLDINGS PLC

16 January 2004

Food and Drug Administration
Information Management Team, HFD-095
5600 Fishers Lane
Rockville, MD 20857

RE: Authorization Letter – Linda M. Duple, Director, North American Regulatory Affairs
Bimeda, Inc.

Please accept this letter as authorization for Linda M. Duple, Director, North American Regulatory Affairs for Bimeda, Inc. to act on behalf of Cross Vetpharm Group in interactions with the Food and Drug Administration. All correspondence regarding facility registration and correspondence from the Center for Veterinary Medicine should be sent to Ms. Duple at 2836 Dolliver Park Avenue, Lehigh, IA 50557.

Should you have questions, please contact me at 011-353-1-451-5011.

Sincerely,

Donal T.M. Tierney
Chief Executive

JAN 29 2004
00003

SUITABILITY PETITION

Submitted by

Cross Vetpharm Group, Inc.

Broomhill Road

Tallaght 24

Dublin, Ireland

For

Phenylbutazone Powder

PETITION

1. Identification

Cross Vetpharm Group
Broomhill Road
Tallaght, 24
Dublin
Ireland

2. Appropriate Citation:

Cross Vetpharm Group, Inc. submits this petition under Section 512 (n)(3) of the Federal Food, Drug and Cosmetic Act.

ACTION REQUESTED

Cross Vetpharm Group, Inc. requests the Commissioner to permit the filing of an extension of the New Animal Drug Application (NADA) for a proposed product that differs from the approved pioneer product.

Pioneer Product

Brand Name:	Butatron Tablets
Company:	Cross Vetpharm Group, Inc.
NADA:	044-756
Active Ingredient:	Phenylbutazone
Species:	Dogs and Horses

Permission is hereby requested to market a granular powder, which contains the same active and inert ingredients as the currently approved tablet, NADA sponsored by Cross Vetpharm Group. Labeling will be revised accordingly.

Proposed Product

Brand Name:	To be determined (Powder)
Company:	Cross Vetpharm Group, Inc.
NADA:	044-756
Active Ingredient:	Phenylbutazone
Species:	Horses

STATEMENT OF GROUNDS

Proposal

In accordance with the 2nd policy letter on the implementation of the Generic Animal Drug and Patent Term Restoration Act, dated June 7, 1989, issued by the Center for Veterinary Medicine, "Change of a Dosage Form", this petition requests a dosage form change. However, we are not requesting the filing of an Abbreviated New Animal Drug Application, but to add the powder dosage form to the existing New Animal Drug Application 044-756. This is a logical extension of the NADA. For this reason, we do not believe that a Bioequivalence Study is required.

Cross Vetpharm proposes that the phenylbutazone tablet granulation that is normally compressed into tablets, also be sold as the uncompressed granulation for equine administration.

Background

Cross Vetpharm's New Animal Drug Application 044-756 provides for the manufacture and sale of Butatron (phenylbutazone) 1-gram tablets for horses. It is our understanding that veterinarians in the field universally instruct horse owners to crush tablets prior to administration. This practice is cumbersome, messy and may result in a lower administered dose due to loss during the crushing operation. Additionally, compounding pharmacies are currently offering an unapproved powder dosage form that is more convenient than the FDA approved tablets.

This request is based upon years of knowledge of manufacturing the granulation as well as the tablet finished dosage form and the universal practice of administering crushed tablets to horses (powder vs. tablet). We believe it is scientifically logical that the uncompressed granulation would be therapeutically comparable to the tablets and the crushed tablets that are actually used in the field.

Supporting Documentation

Bimeda, Inc. has conducted a comparative dissolution study comparing whole tablets, uncompressed granulation and crushed tablets that support our belief that the granulation and tablets (whole and crushed) yield comparative results. The dissolution method used for this study is the same as approved in the Butatron (phenylbutazone) Tablet application. The results of the dissolution study are provided with this Suitability Petition.

In addition, we are providing a letter from Dr. John King, Executive Director of the Board of Minnesota State Veterinary Medicine regarding practices of dosing horses in the field, whereby 1-gram tablets are crushed, and either top dressed with feed or mixed with a syrup.

Labeling

The approved Butatron (phenylbutazone) Tablets under NADA 044-756 bear the federal legend, "Caution: Federal law restricts this drug for use by or on the order of a licensed veterinarian". The proposed labeling also bears the federal legend, providing directions on the amount of powder to be administered based upon weight of horses, in direct correlation to the tablet dosing schedule. Proposed labeling is provided with this Suitability Petition.

Conclusion

Comparative dissolution of the granulation is comparable to the dissolution of the crushed tablets administered in the field and the actual whole tablet. This suitability petition request will allow us to pursue a supplement to Cross' New Animal Drug Application for a powder form Phenylbutazone and provide the horse owner an improved method of dosing. Due to the unique situation, we do not feel submission of a Bioequivalence Waiver or a Bioequivalence Study is required.

ENVIRONMENTAL IMPACT

The submission and review of a suitability petition is a routine administrative and management activity and will not normally be expected to have an environmental impact. We, therefore, hereby request a waiver from the requirements of submitting an environmental impact statement under 21 CFR 25.24 (a)(8) Categorical Exclusions.

ECONOMIC IMPACT

We hereby request a waiver from the requirements of this section for this petition.

CERTIFICATION

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

Linda M. Duple
Director, North American Regulatory Affairs
Bimeda, Inc.
2836 Dolliver Park Avenue
Lehigh, IA 50557
(515) 359-2248

PIONEER LABELING

Indications: Butatron (phenylbutazone tablets, USP) possesses non-hormonal anti-inflammatory properties of value in the management of musculoskeletal conditions such as the arthritides, including osteo-arthritis, in dogs and horses, and as an aid in the relief of inflammation associated with intervertebral disc syndrome in dogs.

Contraindications: DO NOT USE IN MEAT, EGG OR MILK PRODUCING ANIMALS. Do not administer to animals having serious hepatic, cardiac or renal pathology, or those with a history of blood dyscrasia.
Butatron is a Trademark of Bimeda, Inc.

0 61133 57002 0

Manufactured by:
Bimeda, Inc.
Le Sueur, MN 56058

BUTATRON™

(Phenylbutazone Tablets, USP)
1 gram
ANTI-INFLAMMATORY

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

FOR ANIMAL USE ONLY
NOT FOR HUMAN USE
KEEP OUT OF REACH OF CHILDREN
NADA 44-756, Approved by FDA

NET CONTENTS: 100 Tablets

Bimeda

Each tablet contains:
Phenylbutazone U.S.P. . . . . 1 gram
Phenylbutazone is a systemically active anti-inflammatory drug.

Dosage:
Horses: 1-2 grams per 500 lbs. body weight, not to exceed 4 grams daily.

Precautions: In the treatment of inflammatory conditions associated with infection, specific anti-infective therapy is required.

Read package insert carefully for complete instructions prior to use.

Store at controlled room temperature, 20°-25°C (68°-77°F).

Take Time Observe Label Directions

Product No. 1BUT001
Item No. 6BUT001-1001

Lot:
Exp:

INDICATIONS:
Phenylbutazone possesses non-hormonal, anti-inflammatory activity of value in the management of musculoskeletal conditions in dogs and horses such as the arthritides, including osteoarthritis, and as an aid in the relief of inflammation associated with intervertebral disc syndrome in dogs

CONTRAINDICATIONS:
Phenylbutazone should not be administered to animals with serious hepatic, renal or cardiac pathology, or those with a history of blood dyscrasia

WARNING:
PHENYLBUTAZONE SHOULD NOT BE ADMINISTERED TO MEAT, EGG OR MILK PRODUCING ANIMALS BECAUSE THE STATUS OF RESIDUES OF DRUG REMAINING IN EDIBLE TISSUES HAS NOT BEEN DETERMINED.

HAZARDS AND PRECAUTIONS:
1 Use with caution in animals with a history of drug allergy
2. Stop medication at the first sign of gastrointestinal upset, jaundice or blood dyscrasia. Authenticated cases of agranulocytosis associated with phenylbutazone have occurred in man Phenylbutazone induced blood dyscrasias have been reported in dogs. Thrombocytopenia and leukopenia are early manifestations followed by nonregenerative anemia. The occurrence of this reaction is not dose dependent and is unpredictable. To guard against this possibility, conduct routine blood counts at not more than 7 day intervals during the early course of therapy, and at intervals of not more than 14 days throughout the course of therapy Any significant fall in the total white count, relative decrease in granulocytes or black or tarry stools should be regarded as a signal for immediate cessation of therapy and institution of appropriate treatment.
3 When treating inflammatory conditions associated with infection, specific anti-infective therapy is required.
4 Response to phenylbutazone therapy is prompt, usually occurring within 24 hours If no significant clinical response is evident after 5 days of therapy, re-evaluate diagnosis and therapeutic regimen

DOSAGE - DOGS:
ORALLY
20 mg per pound body weight (100 mg/5 lbs.) daily in 3 divided doses, not to exceed 800 mg daily regardless of body weight.

DOSAGE - HORSES:
ORALLY
1-2 grams per 500 lbs. body weight, not to exceed 4 grams daily.

ADMINISTRATION:
1 Use a relatively high dose for the first 48 hours, then reduce gradually to a maintenance dose. Maintain lowest dose capable of producing the desired clinical response
2. In many cases tablets may be crushed and given with feed. Reduce the dosage as symptoms regress. In some cases treatment may be given only when symptoms appear with no need for continuous medication.
3 In animals, phenylbutazone is largely metabolized in 8 hours. It is recommended that a third of the daily dose be administered at 8 hour intervals.
4. Many chronic conditions will respond to phenylbutazone therapy but discontinuance of treatment may result in the recurrence of symptoms.

STORAGE:
Store at controlled room temperature, 20°-25° C (68° - 77° F).

HOW SUPPLIED:
BUTATRON™ (Phenylbutazone Tablets, U.S.P.) are supplied in the following tablet concentrations and package sizes:

100 mg tablets	Bottles of 1000 tablets
1 gram tablets	Bottles of 100 tablets

REFERENCES:

1 Kuzell, W C., Schaffarzick, R W., Naugler, W G , Mankle, E A., A M.A. Arch Int Med 92:646,1953.
2. Kuzell, W.C., Schaffarzick, R.W , Brown, B., Mankle, E A , Jour Amer. Med Assoc. 149:729,1952
3 Kuzell, W.C , Schaffarzick, R.W , Cal Med. 77 319,1952
4 Payne, R.W., Shetlar, M R., Farr, C., Hellbaum, A.A , and Ishmael, W K.T , J. Lab Clin Med 45 331,1955.
5 Flemming, J. and Will, G., Ann. Rheumat. Dis 12:95,1953.
6 Denko, C W., Ruml, D , Amer Practit. 6:1865,1955
7 Fabre, J. and Berger, A., Semaine Hop (Paris) 31:87,1955
8. Domenjoz, R., Theobald, W and Morsdorf, K., Arzneimittel-Forsch 5:488,1955
9 Wilhelmi, G and Pulver, R., Arzneimittel-Forsch 5.221,1955.

h, N , Paton, B., Brodie, B.B and Burns, J.J , A.M.A. Arch Ophth.
4 1955.
man, L.L., Jour. A.V.M.A 125:128,1954
a, J O., Vet. Rec. 68:60 (Jan 21), 1956.
e, F.B. and Sutter, M.B , Vet. Med. 52:492-494,1957.
eros, H.R., Rev. Med. Vet. (Buenos Aires) 38:9,1956.
M.D., Vet. Med. 58:83 (Feb.), 1958.

FOR ANIMAL USE ONLY
NOT FOR HUMAN USE
KEEP OUT OF REACH OF CHILDREN

Manufactured by
Bimeda, Inc.
Le Sueur, MN 56058

502

BUTATRON™

Phenylbutazone Tablets USP
NADA 44-756, Approved by FDA

CAUTION:
Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:
Phenylbutazone is a non-hormonal, anti-inflammatory agent. Chemically, it is described as 4-Butyl-1,2-diphenyl-3,5 pyrazolidinedione, a synthetic pyrazolone derivative, entirely unrelated to the steroid compounds.

ACTIONS AND USES:
Kuzell(1,2,3), Payne(4), Flemming(5) and Denko(6), demonstrated clinical effectiveness of phenylbutazone in acute rheumatism, gout, gouty arthritis and various other rheumatoid diseases in man. Anti-inflammatory activity has been well established by Fabre(7), Domenjoz(8), Wilhelmi(9), and Yournsh(10).

Lieberman(11) reported on the effective use of phenylbutazone in the treatment of conditions of the musculoskeletal system in dogs, including posterior paralysis associated with intervertebral disc syndrome, fractures, arthritis and injuries to the limbs and joints. Joshua(12) observed objective improvement without toxicity following long-term therapy of two aged arthritic dogs. Ogilvie and Sutter(13) reported rapid response to phenylbutazone therapy in a review of 19 clinical cases including posterior paralysis, posterior weakness, arthritis, rheumatism and other conditions associated with lameness and musculoskeletal weakness

Camberos(14) reported favorable results with phenylbutazone following intermittent treatment of thoroughbred horses for arthritis and chronic arthrosis (e.g. osteoarthritis of medial and distal bones of the hock, arthritis of the stifle and hip, arthrosis of the spine and generalized arthritis). Results were less favorable in cases of traumatism, muscle rupture, strains and inflammatory conditions of the third phalanx. Sutter(15) reported favorable responses in chronic equine arthritis, fair results in a severely bruised mare, and poor results in two cases where the condition was limited to the third phalanx.

PROPOSED LABELING

1. Identification of a trade name has not yet been determined.
2. Company name and logo remain the same.
3. References to dogs on the label have been deleted.
4. Provided for administration of powder (either top dressed or mixed with syrup).

Indications: Tradename (phenylbutazone) Powder possesses non-hormonal anti-inflammatory properties of value in the management of musculoskeletal conditions such as the arthritides, including osteoarthritis in horses.

Contraindications: DO NOT USE IN MEAT, EGG OR MILK PRODUCING ANIMALS. Do not administer to animals having serious hepatic, cardiac or renal pathology, or those with a history of blood dyscrasia.

Read package insert carefully for complete instructions prior to use

Take time observe label directions

Manufactured by:

Bimeda, Inc.

Le Sueur, MN 56058

TRADENAME POWDER

(Phenylbutazone)

Anti-Inflammatory

For Oral Use in Horses Only

For Animal Use Only
Not for Human Use
Keep Out of Reach of Children

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

ANADA 044-756, Approved by FDA

Net Contents:

Each heaping teaspoon contains:
Phenylbutazone U.S.P..... 1 gram

One (1) heaping teaspoon (3 grams of powder) provides 1 gram of phenylbutazone.

Phenylbutazone is a systemically active anti-inflammatory drug.

Dosage:
Horses 1-2 grams per 500 lbs. body weight, not to exceed 4 grams daily

Precautions: In the treatment of inflammatory conditions associated with infection, specific anti-infective therapy is required.

Store at controlled room temperature, 20°C - 25°C (68° - 77°F)

Lot:

Exp:

TRADENAME POWDER

(Phenylbutazone)

NADA 044-756, Approved by FDA

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: Phenylbutazone is a non-hormonal, anti-inflammatory agent. Chemically, it is described as 4-Butyl-1,2-diphenyl-3,5 pyrazolidinedione, a synthetic pyrazolone derivative, entirely unrelated to the steroid compounds.

ACTIONS AND USES: Kuzell(1,2,3), Payne(4), Flemming(5) and Denko(6), demonstrated clinical effectiveness of phenylbutazone in acute rheumatism, gout, gouty arthritis and various other rheumatoid diseases in man. Anti-inflammatory activity has been well established by Fabre(7), Domenjoz(8), Wilhelmi(9), and Yourish(10).

Lieberman(11) reported on the effective use of phenylbutazone in the treatment of conditions of the musculoskeletal system in dogs, including posterior paralysis associated with intervertebral disc syndrome, fractures, arthritis and injuries to the limbs and joints. Joshua(12) observed objective improvement without toxicity following long-term therapy of two aged arthritic dogs. Ogilvie and Sutter(13) reported rapid response to phenylbutazone therapy in a review of 19 clinical cases including posterior paralysis, posterior weakness, arthritis, rheumatism and other conditions associated with lameness and musculoskeletal weakness.

Camberos(14) reported favorable results with phenylbutazone following intermittent treatment of thoroughbred horses for arthritis and chronic arthrosis (e.g. osteoarthritis of medial and distal bones of the hock, arthritis of the stifle and hip, arthrosis of the spine and generalized arthritis). Results were less favorable in cases of traumatism, muscle rupture, strains and inflammatory conditions of the third phalanx. Sutter(15) reported favorable responses in chronic equine arthritis, fair results in a severely bruised mare, and poor results in two cases where the condition was limited to the third phalanx.

INDICATIONS: Phenylbutazone possesses non-hormonal, anti-inflammatory activity of value in the management of musculoskeletal conditions in horses such as arthritides, including osteoarthritis.

CONTRAINDICATIONS: Phenylbutazone should not be administered to animals with serious hepatic, renal or cardiac pathology, or those with a history of blood dyscrasia.

WARNING: PHENYLBUTAZONE SHOULD NOT BE ADMINISTERED TO MEAT, EGG OR MILK PRODUCING ANIMALS BECAUSE THE STATUS OF RESIDUES OF DRUG REMAINING IN EDIBLE TISSUES HAS NOT BEEN DETERMINED.

HAZARDS AND PRECAUTIONS:

1. Use with caution in animals with a history of drug allergy.
2. Stop medication at the first sign of gastrointestinal upset, jaundice or blood dyscrasia. Authenticated cases of agranulocytosis associated with phenylbutazone have occurred in man. Phenylbutazone induced blood dyscrasias have been reported in dogs. Thrombocytopenia and leukopenia are early manifestations followed by nonregenerative anemia. The occurrence of this reaction is not dose dependent and is unpredictable. To guard against this possibility, conduct routine blood counts at nor more than 7 day intervals during the early course of therapy, and at intervals of not more than 14 days throughout the course of therapy. Any significant fall in the total white count, relative decrease in granulocytes or black or tarry stools should be regarded as a signal for immediate cessation of therapy and institution of appropriate treatment.
3. When treating inflammatory conditions associated with infection, specific anti-infective therapy is required.
4. Response to phenylbutazone therapy is prompt, usually occurring within 24 hours. If no significant clinical response is evident after 5 days of therapy, re-evaluate diagnosis and therapeutic regimen.

DOSAGE – HORSES:

ORALLY – 1-2 grams per 500 lbs. body weight, not to exceed 4 grams daily. One (1) heaping teaspoon (3 grams of powder) provides 1 gram of phenylbutazone.

ADMINISTRATION:

1. Use a relatively high dose for the first 48 hours, then reduce gradually to a maintenance dose. Maintain lowest dose capable of producing the desired clinical response.

2. Powder may be given with feed Reduce the dosage as symptoms regress. In some cases treatment may be given only when symptoms appear with no need for continuous medication.

3. In animals, phenylbutazone is largely metabolized in 8 hours. It is recommended that a third of the daily dose be administered at 8 hour intervals.

4. Many chronic conditions will respond to phenylbutazone therapy but discontinuance of treatment may result in the recurrence of symptoms.

STORAGE:

Store at controlled room temperature, 20° - 25°C (68° - 77°F).

HOW SUPPLIED:

TRADENAME (phenylbutazone) Powder is supplied in the following package sizes:

REFERENCES:

1. Kuzell, W.C., Schaffarzick, R.W., Naugler, W.G., Mankle, E.A., A.M.A. Arch. Int. Med 92:646, 1953.
2. Kuzell, W.C., Schaffarzick, R.W., Brown, B., Mankle, E.A., Jour Amer. Med. Assoc. 149:729, 1952.
3. Kuzell, W.C., Schaffarzick, R.W., Cal. Med. 77:319, 1952.
4. Payne, R.W., Shetlar, M.R., Farr, C., Hellbaum, A.A., and Ishmael, W.K.T., J. Lab. Clin. Med. 45:331, 1955.
5. Flemming, J. and Will, G., Ann. Rheumat. Dis. 12:95, 1953.
6. Denko, C.W., Ruml, D., Amer. Practit. 6:1865, 1955.
7. Fabre, J. and Berger, A., Semaine Hop. (Paris) 31:87, 1955.
8. Domenjoz, R., Theobald, W. and Morsdorf, K., Arzneimittel-Forsch. 5:488, 1955.
9. Wilhelmi, G. and Pulver, R., Arzneimittel-Forsch. 5:221, 1955.
10. Yourish, N., Paton, B., Brodie, B.B. and Burns, J.J., A.M.A. Arch. Ophth. 53:264, 1955.
11. Lieberman, L.L., Jour. A.V.M.A. 125:128, 1954.
12. Joshua, J.O., Vet. Rec. 68:60 (Jan. 21), 1956.
13. Ogilvie, F.B. and Sutter, M.B., Vet. Med. 52:492-494, 1957.
14. Camberos, H.R., Rev. Med. Vet. (Buenos Aires) 38:9, 1956.
15. Sutter, M.D., Vet. Med 58:83 (Feb.), 1958.

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KEEP OUT OF REACH OF CHILDREN

Manufactured by:
Bimeda, Inc.
Le Sueur, MN 56058

Phenylbutazone Granulation Comparative Dissolution

We are proposing to the FDA that the Phenylbutazone granulation should be allowed as an extension of the Phenylbutazone tablet NADA.

A comparative dissolution study was performed using whole tablets, crushed tablets (field use) and uncompressed granulation. The data is provided below.

1. Whole Tablet Dissolution

Minutes	*Average of 3*
6.00	47.33
12.00	62.78
18.00	70.77
24.00	75.31
30.00	80.13

2. Granulation, uncompressed

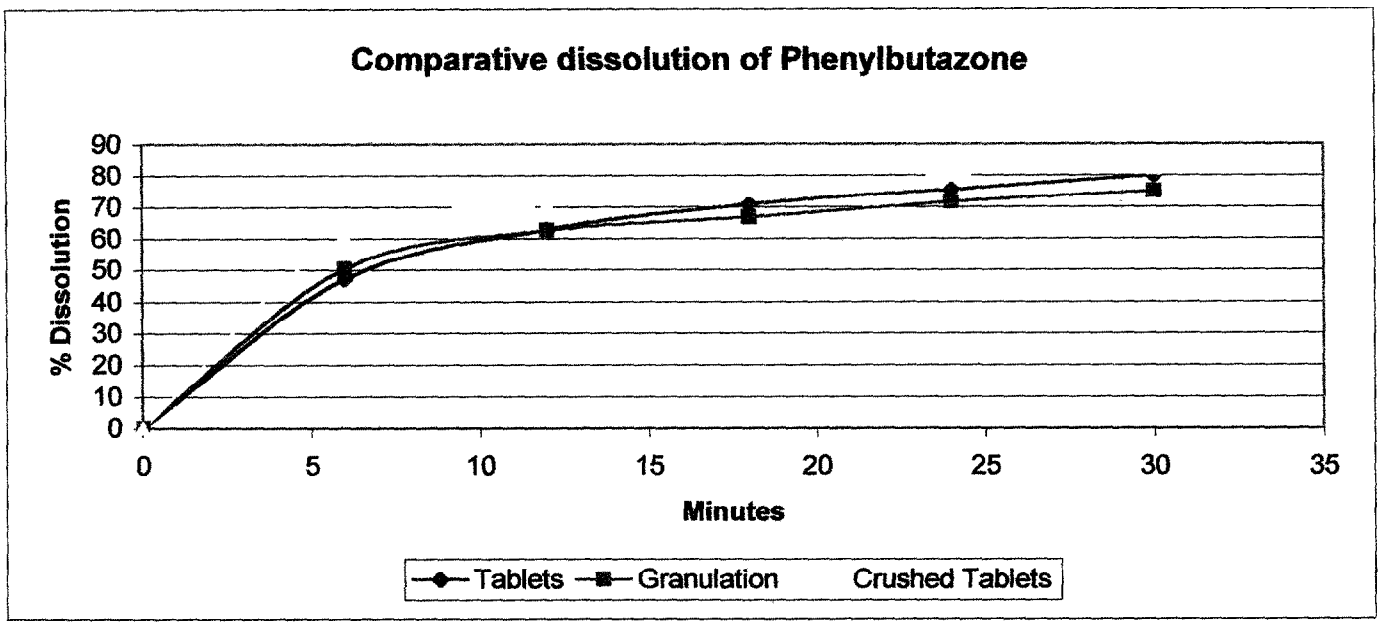
Minutes	*Average of 3*
6	50.38
12	62.58
18	66.76
24	71.55
30	75.07

3. Crushed tablets (field use)

Minutes	*Average of 3*
6	60.81
12	70.69
18	75.19
24	80.09
30	82.23

4. Summary Table for Graphing

Minutes	Tablets	Granulation	Crushed Tablets
0	0	0	0
6	47.33	50.38	60.81
12	62.78	62.58	70.69
18	70.77	66.76	75.19
24	75.31	71.55	80.09
30	80.13	75.07	82.23



MINNESOTA BOARD OF VETERINARY MEDICINE

2829 University Avenue SE #540
Minneapolis, MN 55414-3250
Ph: 612-617-2170 Fax: 612-617-2172
MN Relay Service for Hearing/Speech Impaired: 800-627-3259
E-mail: vet.med@state.mn.us Website: www.vetmed.state.mn.us

January 7, 2004

Paul Rice
Bimeda Inc
291 Forest Prairie Road
Le Sueur, MN 56058
Phone: (507) 665 3316

Dear Paul;

As requested, I am writing a letter to document our phone discussions regarding the use of Phenylbutazone tablets, 1 gram, in the field. The following is to the best of my recollection of your questions and my responses.

1. Are 1-gram Phenylbutazone tablets routinely crushed before administration to the Horse?

Horses are browsers. They would not eat a whole Phenylbutazone tablet in the feed. They would avoid the tablet while eating. Veterinarians dispense the correct number of tablets, but instruct the owner to crush the tablets before top dressing the feed. I usually instruct the owners to place the tablets in a ziplock baggie and then pound the baggie with a hammer until the tablets become a powder. The baggie is then opened and the powder is added to the feed. Other veterinarians may recommend other methods of crushing the tablets. In some cases, the horse will refuse to eat the top dressed feed. In these cases, I recommend mixing the powder with a sweet syrup (e.g. pancake syrup, molasses, etc) and adding the syrup to the feed or feeding the syrup directly to the horse.

2. Are the whole tablets ever given to a Horse?

Ever? Nothing is impossible. A rare number of Veterinarians may use a balling gun as a matter of preference, however it is a dangerous practice for the horse and owner. Horses are likely to swing their head during administration and the long balling gun can cause injury to the esophagus and palate. Horses are more skittish than cows and are likely to thrash out with their front feet and throw their head. In addition most horse owners have not had experience with balling guns unless they have had previous experience with cows.

3. Estimate of % crushed tablets vs. % whole tablets administered in the field?

I estimate over 90% based on my personal experience. I can recall only 1 person who administered the tablets with a balling gun. That person was collecting mare urine (for Premarin) and the horses were in a tie stall and were handled extensively.

4. How long have Veterinarians routinely crushed Phenylbutazone tablets for horses?

I believe they have been crushed since they first became available in the marketplace. Horses have not changed over the years. If horse owners put the tablet on the feed, it would not be eaten whether it was today or 20 years ago.
I understand you have also contacted my father, Jack king, DVM, who agreed that the tablets were not routinely administered as whole tablets even when they were first marketed. All of my colleagues that I have discussed this topic with recommend to their clients to crush the tablets prior to administration in the feed.

Availability of Powder is a great convenience to the practitioner in the field and their client. Flavored powders would greatly enhance palatability. Currently powder is only available through compounding pharmacies.

If you need any additional information, please call me at 612 -617-2170.

Sincerely,

John King DVM

Dr John King, DVM

JAN 29 2004

00021