DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 8-848/S-024

Bradley Pharmaceuticals
c/o: Cato Research
Attn: Dr. Kevin Barber
Westpark Corporate Center
4364 South Alston Avenue
Durham, North Carolina 27713-2280

Dear Dr. Barber:

Please refer to your supplemental new drug application dated November 22, 2002, received November 25, 2002, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Pamine® (methscopolamine bromide) Tablets.

We acknowledge receipt of your submission dated November 22, 2002. Your submission of November 22, 2002 constituted a complete response to our February 28, 2002 action letter.

This supplemental new drug application provides for a 5-mg tablet and a proposed name (Pamine® Forte) for the new strength.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The final printed labeling (FPL) must be identical to the labeling contained in your November 22, 2002 submission.

Please submit the FPL electronically according to the guidance for industry titled, "Providing Regulatory Submissions in Electronic Format – NDA." Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 8-848/S-024." Approval of this submission by FDA is not required before the labeling is used.

Although not required for approval of this supplement, please consider the following recommendations for labeling revisions at the next printing:

A. 100 Tablet Bottle Label

1. Ensure that the container labels for Pamine and Pamine Forte are adequately differentiated in their design and use of color. The background color behind Pamine Forte should be a lighter color than the orange used on the Pamine container label.

2. Revise the "Each Pamine Tablet contains" statement to read, "Each Pamine Forte Tablet contains…"

3. Consider addition of a barcode that contains the 10-digit NDC number.

4. Increase the prominence of the product strength. It may be beneficial to relocate it to appear following the established name rather than between the proprietary and established names.

B. 4 Tablet Sample Blister Strip

1. Include an "Each Pamine Forte Tablet contains…" statement to prevent confusion that leads patients to think that four tablets equal 5 mg.

2. In accordance with the Poison Prevention Act, drugs packaged in "unit of use" bottles and dispensed on an outpatient basis, such as the 30 capsule bottles, should include Child Resistant Closures (CRC). Please ensure this unit-of-use bottle utilizes such a closure.

3. See comment A.4. above.

C. 6 Tablet Sample Package

1. Revise the "Each Pamine Tablet contains" statement to read, "Each Pamine Forte Tablet contains…"

2. Consider eliminating one of the Sample packages so that there is either a sample of 6 tablets or 4 tablets.

3. Include the word "Sample" prior to "Not for Sale" on the container label.

4. In accordance with the Poison Prevention Act, drugs packaged in "unit of use" bottles and dispensed on an outpatient basis, such as the 30 capsule bottles, should include Child Resistant Closures (CRC). Please ensure this unit-of-use bottle utilizes such a closure.

5. See comment A.4. above.

D. Package Insert

1. It appears that Pamine and Pamine Forte will share common insert labeling. This could create some confusion if both product names are not prominently displayed at the top of the insert. Revise accordingly.

2. The DOSAGE AND ADMINISTRATION section states, "If the patient is having **severe symptoms** which demand prompt relief, the drug may be started on a daily dosage of 20 mg, administered in doses of 5 mg one-half hour before meals and at bedtime. Consider adding a specific description of **severe symptoms** in this section.

3. Consider adding a specific description of **"very unpleasant side effects"** in this section.

4. Revise the HOW SUPPLIED section to include "Pamine Forte".

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ryan Barraco, Regulatory Project Manager, at (301) 827-0191.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Justice

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