DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 8-848/S-025 **CBE-30 SUPPLEMENT**

Bradley Pharmaceuticals, Inc.
Attention: Bohdan M. Ferenc
Director, Regulatory Affairs and Quality Assurance
383 Route 46 West
Fairfield, NJ 07004-2402

Dear Mr. Ferenc:

Please refer to your supplemental new drug application dated April 30, 2004, received May 5, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pamine® and Pamine® Forte (methscopolamine bromide) Tablets.

We acknowledge receipt of your submissions dated June 3, June 9, July 26, and November 16, 2004.

Your submission of November 16, 2004 constituted a complete response to our November 5, 2004 action letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate manufacturing/packaging/testing site, **(b)(4)** .

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 9 and July 26, 2004.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ryan Barraco, Consumer Safety Officer, at 301-443-8017.

Sincerely,

{See appended electronic signature page}

Liang Zhou, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal & Coagulation Drug Products, HFD-180
Division of New Drug Chemistry II,
Office of New Drug Chemistry
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/

Liang Zhou

5/16/05 11:56:04 AM