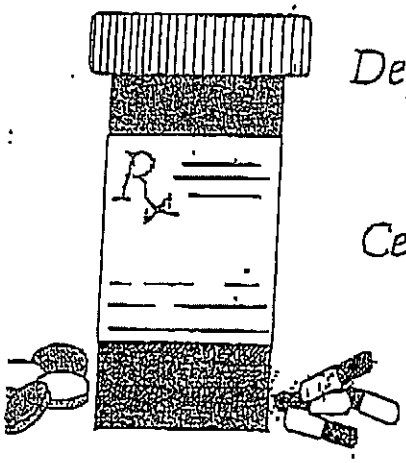
FAX COVER SHEET



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Rockville, Maryland

Date: 5/29/08

To: Mr. Dana Toops
X~~3303~~

Phone: 3368128676 2331 Fax: 336-812 9091

FROM: *Simon Eng*

Phone 240-276-8529 FAX: 240-376-8504

Number of pages: 4 including cover sheet

Comments: *Congrats!*

ANDA N/A has been tentatively approved!

ANDA 78720 has been approved!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-720

Banner Pharmacaps, Inc.
Attention: Dana S. Toops
Director, Regulatory Affairs
4125 Premier Drive
High Point, NC 27265

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 21, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Amantadine Hydrochloride Capsules USP, 100 mg.

Reference is also made to your amendments dated May 16, July 17, and August 30, 2007; and February 5, February 22, March 26, May 7 (2 submissions), and May 23, 2008.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Amantadine Hydrochloride Capsules USP, 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Amantadine Hydrochloride Capsules USP, 100 mg, of USL Pharma Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

(See appended electronic signature page)

Gary Buehler
Director
Office of Generic Drugs
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 L. West
5/29/2008 07:48:45 AM
Deputy Director, for Gary Buehler