DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 062713/S-004 and S-005

Belcher Pharmaceuticals Inc.
Attention: Ram Mohan Kathuroji
12393 Belcher Road Suite 420
Largo, FL 33773

Dear Sir:

This is in reference to your supplemental new drug applications dated March 10, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Cephalexin Capsules USP, 250 mg and 500 mg.

Reference is also made to your amendments dated May 11, 2006; September 21, 2007; April 17, 2009, May 26, 2009, and October 2, 2009; May 7, 2010, November 9, 2010, and February 10, 2011.

The supplemental applications, submitted as "Prior Approval Supplements," provide for a manufacturing site change for Cephalexin Capsules.

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

{See appended electronic signature page}

Vilayat A. Sayeed, Ph.D.
Director
Division of Chemistry III
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 ISER
05/04/2011
Acting Director