DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 75-047/S-006

Amneal Pharmaceuticals of NY LLC
Attention: Arlin Frias
75 Adams Avenue
Hauppauge, NY 11788

Dear Madam:

This is in reference to your supplemental new drug application dated February 6, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Acebutolol Hydrochloride Capsules USP, 200 mg and 400 mg.

The supplemental application, submitted as a "Supplement: Changes Being Effected in 30 Days," provides for addition of the following manufacturing and testing sites and concomitant changes to the labeling components for Acebutolol Hydrochloride Capsules USP, 200 mg and 400 mg. The requested site changes and their functions are listed below.

Change	
Site Change: Manufacturing, Testing of API, Excipients, Packaging Components, Finished Product and Stability	To, Amneal Pharmaceuticals 50 Horseblock Road Brookhaven, NY: 11719
Site Change: Encapsulation, Packaging, Testing of API, Excipients, Packaging Components, Finished Product and Stability)	To, Amneal Pharmaceuticals 75 Adams Avenue, Hauppauge NY: 11788
Site Change: Alternate Contract Laboratory for testing of Inactive Ingredients	Celsis Laboratories 165 field crest avenue Edison, NJ: 08837

We have completed the review of this supplemental application and it is approved.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-75047	SUPPL-6	AMNEAL PHARMACEUTICAL	ACEBUTOLOL HYDROCHLORIDE

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

/s/

RICHARD C ADAMS
12/03/2009