

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078780

Amneal Pharmaceuticals of NY LLC
Attention: Alpesh Patel
Senior Director, Global Regulatory Affairs
85 Adams Avenue
Hauppauge, NY 11788

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 28, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cetirizine Hydrochloride Tablets, (OTC), 5mg and 10 mg.

Reference is also made to your amendments dated July 2, November 14, and December 20, 2007; January 1, June 23, July 30 and December 30, 2008; and February 5 and November 16, 2009.

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 over-the-counter (OTC) 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 Cetirizine Hydrochloride Tablets, 5mg and 10 mg to be bioequivalent to the reference listed drug, Zyrtec Allergy Tablets, 5 mg and 10 mg and Zyrtec Hives Relief Tablets, 5 mg and 10 mg, of McNeil Consumer Healthcare. 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.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "**Miscellaneous Correspondence - SPL for Approved ANDA 078780**".

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research