DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090229

Synthon Pharmaceuticals, Inc.
Attention: Shannon F. Holmes, Ph.D.
Senior Regulatory Affairs Specialist
9000 Development Drive
P.O. Box 110487
Research Triangle Park, North Carolina 27709

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 17, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Levocetirizine Dihydrochloride Tablets, 5 mg.

Reference is also made to your amendments dated May 12, and June 2, 2008; June 25, 2009; and March 11, April 30, August 20, September 23, October 15, and November 17, 2010. We also acknowledge receipt of your correspondences dated February 29, and April 17, 2008; and June 29, September 13, and October 1, 2010, pertaining to the patent and exclusivity issues associated with this ANDA.

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 Levocetirizine Dihydrochloride Tablets, 5 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Xyzal Tablets, 5 mg, of UCB, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, UCB's Xyzal Tablets, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S.

Patent No. 5,698,558 (the '558 patent), is scheduled to expire on March 24, 2013, with pediatric exclusivity added.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the ‘558 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Levocetirizine Dihydrochloride Tablets, 5 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Synthon Pharmaceuticals, Inc. (Synthon) for infringement of the listed '558 patent. You have notified the agency that Synthon complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '558 patent was initiated against Synthon within the statutory 45-day period in the United States District Court for the District of North Carolina [Sepracor Inc., UCB S.A., and UCB, Inc. v. Synthon Pharmaceuticals, Inc., Synthon Holding B.V., Synthon B.V., and Synthon Laboratories, Inc., Civil Action No. 08-0179; and in the District of Delaware, Civil Action No. 08-0207]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Synthon was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '558 patent. Therefore, with this approval, Synthon is eligible for 180-days of generic drug exclusivity for Levocetirizine Dihydrochloride Tablets, 5 mg.[1] This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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.

[1] The agency has determined that there was a change in the requirements for approval of this ANDA. Specifically, the labeling of the RLD changed after submission of the ANDA. The agency has also determined that this change was the cause of your not obtaining tentative approval of the ANDA within 30 months after the date on which it was filed. See section 505(j)(5)(D)(IV) of the Act.

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 section 505-1(i) of the Act.

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] 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 (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

11/26/2010

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.