ANDA 078703

OFFICE OF GENERIC DRUGS

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North VII
7620 Standish Place
Rockville,MD 20855
Fax: 240-276-9327

FAX TRANSMISSION COVER SHEET

APPLICANT: GlaxoSmithKline TEL: 919-483-5857

ATTN: Mary Faye S. Whisler, Ph.D. FAX: 919-315-4364

FROM: Frank J. Nice FDA CONTACT PHONE: 240-276-8555

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated , submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Propranolol Hydrochloride Extended Release Capsules USP, 60 mg, 80 mg, 120 mg, and 160 mg.

We are pleased to inform you that this application is APPROVED!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078703

SmithKline Beecham Corporation
Attention: Mary Faye S. Whisler
Assistant Director, CMC Regulatory Affairs
Five Moore Drive
P.O Box 13398
Research Triangle Park, NC 27709

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 20, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Propranolol Hydrochloride Extended-release Capsules USP, 60 mg, 80 mg, 120 mg and 160 mg.

Reference is also made to your amendments dated March 19, May 1, September 13, and December 13, 2007; March 19, and November 4, 2008; August 4, 2009; January 29, October 22, 2010; and March 3, March 25, April 5, May 10, June 14 2011.

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 Propranolol Hydrochloride Extended-release Capsules USP, 60 mg, 80 mg, 120 mg and 160 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Inderal LA Extended-release Capsules, 60 mg, 80 mg, 120 mg and 160 mg, respectively, of Akrimax Pharmaceuticals, LLC.

Your dissolution testing should be incorporated into the stability and quality control program using the same USP Test 1 method proposed in your application. The "interim" dissolution specifications are as follows:

Apparatus: USP apparatus I (Basket) at 100 rpm

Medium: Acid Stage: 900 mL of pH 1.2 Buffer solution for 1.5 hours, followed by

Buffer Stage: 900 mL of buffer solution at pH 6.8 for the specified time.

The drug product should meet the following "interim" specifications:

Time (Hours)	Percent Dissolved
1.5	NMT 30
4	35-60
8	55-80
14	70-95
24	81-110

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement - Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

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.

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 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
07/15/2011
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.