



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Food and Drug Administration  
Rockville, MD 20857

ANDA 76-862

Watson Laboratories, Inc. - Florida  
Attention: Janet Vaughn  
Director, Regulatory Affairs  
2945 West Corporate Lakes Blvd.  
Weston, FL 33331

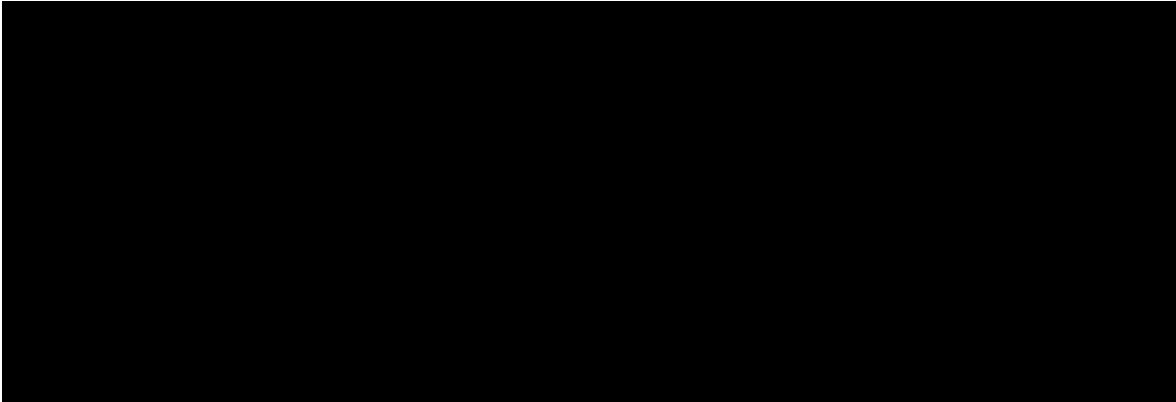
Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 8, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Metoprolol Succinate Extended-release Tablets USP, 50 mg.

Reference is also made to your amendments dated March 18, and June 2, 2005; February 9, March 2, October 11, and November 6, 2006; February 19, April 30, June 1, September 11, and September 12, 2007; December 5, 2008; and February 11, February 27, March 5, March 20, May 22, July 10, and July 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 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 Metoprolol Succinate Extended-release Tablets USP, 50 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Toprol-XL Extended-release Tablets, 50 mg, of AstraZeneca LP.

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



The "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 Effectuated" 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.

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/oc/datacouncil/spl.html>, 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 76-862".

Sincerely yours,

*{See appended electronic signature page}*

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

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

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/s/

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SIMON S ENG  
08/03/2009

ROBERT L WEST  
08/03/2009  
Deputy Director, for Gary Buehler