



ANDA 40-759

Wockhardt USA Inc.  
Attention: Brij Khera  
SR VP Intellectual Property  
U.S. Agent for Wockhardt Limited  
135 US Route 202/206  
Bedminster, NJ 07921

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated February 23, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Extended Phenytoin Sodium Capsules USP, 30 mg.

Reference is also made to your amendments dated January 15, February 6, and October 4, 2007.

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 Extended Phenytoin Sodium Capsules USP, 30 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Dilantin®(Extended Phenytoin Sodium Capsules, 30 mg), of Parke Davis.

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:

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:

Dissolution Testing should be conducted in 900 mL of water using apparatus 1 (basket) at 50 rpm.

<u>Time (minutes)</u>	<u>Percent Dissolved</u>
30	NMT 
60	 (Q)
120	NLT 

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement - Changes Being Effected when there are no revisions to the "interim" specifications or when 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.

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(s) 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.

Sincerely yours,

*{See appended electronic signature page}*

Gary Buehler  
Director  
Office of Generic Drugs  
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  
12/18/2007 02:42:53 PM  
for Gary Buehler