



NDA 022032/S-012

**SUPPLEMENT APPROVAL**

Lachman Consultant Services, Inc.  
Attention: Mary-Anne D'Esposito, M.Sc.  
Manager  
Agent for Dexcel Pharma Technologies Limited  
1600 Stewart Avenue  
Westbury, New York 11590

Dear Ms. D'Esposito:

Please refer to your Supplemental New Drug Application (sNDA) dated January 5, 2011, received January 6, 2011, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed-release tablets, 20mg.

We acknowledge receipt of your amendment dated March 2, 2011.

This "Changes Being Effected" supplemental new drug application provides for the revision of the current bulleted statement, "taking warfarin or clopidogrel (blood-thinning medicine)," under the Drug Facts Warnings subheading, "**Ask a doctor or pharmacist before use if you are taking**" to read:

- "Ask a doctor or pharmacist before use if you are taking**
- warfarin, clopidogrel or cilostazol (blood-thinning medicines)"

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

**LABELING**

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (the 14-count immediate container (bottle) label, 14-, 28- and 42-count carton labels for bottle packaging; 14-count inner carton and 14-, 28- and 42-count outer carton labels for blister packaging; and consumer information leaflet submitted on March 2, 2011), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Even though no revisions were made to the immediate container (blister card), we request that you submit this label as part of the FPL for this supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

The final printed labeling should be submitted electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 022032/S-012.**” Approval of this submission by FDA is not required before the labeling is used.

### **DRUG REGISTRATION AND LISTING**

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Mary Vienna, Regulatory Project Manager, at (301) 796-4150.

Sincerely,

*{See appended electronic signature page}*

Joel Schiffenbauer M.D.  
Deputy Director  
Division of Nonprescription Clinical Evaluation  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

### **ENCLOSURES:**

Carton and Container Labeling

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

/s/  
-----

JOEL SCHIFFENBAUER  
06/27/2011