DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022032/S-016

SUPPLEMENT APPROVAL

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

Dear Ms. D'Esposito:

Please refer to your Supplemental New Drug Application (sNDA) dated October 10, 2011, received October 11, 2011 pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed-release tablets, 20 mg.

This "Prior Approval" supplemental new drug application proposes the following changes:

- The removal of the consumer information leaflet (CIL)
- The addition of the "Tips for Heartburn" to the carton labels
- The removal of the reference to the CIL in the "Other Information" section of the "Drug Facts" label
- Delete the "Warnings," "Directions" and "Inactive Ingredients" sections of the "Drug Facts" label on the bottle immediate containers
- Revise the storage statement on the "Drug Facts" label
- The addition of "Swallow whole. Do not chew or crush tablet." to the immediate container (blister) label

We have completed our review of this application. 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 14-count immediate container (bottle) label; 14-, 28-, and 42-count carton labels for the bottle container closure system; the 7- and 14-count immediate container (blister) label and 14-count inner carton and 14-, 28-, and 42 count outer carton labels for the blister container closure systems submitted on October 10, 2011 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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 22032/S-16**." 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.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D., M.S.
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/

ANDREA LEONARD SEGAL
04/09/2012