DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022032/S-008

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 22, 2010, received January 25, 2010, 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 amendments dated March 26, June 23 and July 8, 2010.

This "Changes Being Effected" supplemental new drug application provides for the addition of a warning statement "Ask a doctor or pharmacist before use if you are taking: Clopidogrel bisulfate (anti-blood clotting medicine)" and the addition of a toll-free poison control telephone number to the Drug Facts labeling.

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 and with the minor editorial revisions listed below.

1. Carton (for bottle packaging configuration): ensure that the statement "acid reducer" on the PDP has sufficient contrast to be legible (14-, 28-, 42-count).

2. Immediate container (bottle) label: ensure that the statement "acid reducer" on the PDP has sufficient contrast to be legible.

3. Outer carton (for blister packaging configuration): revise the 20 mg product strength statement's font color on the PDP to be consistent for all counts (14-, 28-, and 42-count).

4. Outer carton (for blister packaging configuration): ensure that the statement "acid reducer" on the PDP has sufficient contrast to be legible (14-count).

5. Drug Facts (cartons for bottle packaging configuration, immediate container (bottle) label , inner carton for blister packaging configurations, outer carton for blister packing configuration, and Drug Facts label content for package insert): under the heading Warnings, subheading: "Ask a doctor or pharmacist before use if you are", delete the "s" from "medicines" and replace with "(bullet) warfarin or clopidogrel (blood-thinning medicine)".

Submit final printed labeling, except with the revisions listed above, 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 submitted June 23, 2010 (14-count inner carton for blister packaging configuration; 14-, 28-, 42-count outer carton labels for blister packaging configuration; package insert; 14-count immediate container bottle label; and 14-, 28-, 42-count carton labels for bottle packaging configuration), 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 (October 2005)". 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-008**." Approval of this submission by FDA is not required before the labeling is used.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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}

Andrea Leonard Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE:
Carton and Container Labeling, Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22032	SUPPL-8	DEXCEL PHARMA TECHNOLOGIES LTD	OMEPRAZOLE DELAYED RELEASE TABLETS 20MG

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
07/16/2010