DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-032/S-003

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 dated October 9, 2008, received October 10, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for omeprazole delayed-release tablets, 20 mg.

We acknowledge receipt of your submission dated March 19, 2009.

This supplemental application proposes the addition of a website address statement, "TreatMyHeartburn.com" with an accompanying graphic to the outer carton labels, the addition of the statement "24 Hour Heartburn Blocker" to the outer carton labels and the addition of a toll-free telephone number to the "Questions or comments?" section of the Drug Facts for the 14-, 28-, and 42-count outer cartons.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (14-count outer (retail) carton submitted October 9, 2008 and the 28- and 42-count outer (retail) carton label submitted March 19, 2009) and must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 22-032/S-003**." Approval of this submission by FDA is not required before the labeling is used.

Per your March 19, 2009 commitment, we remind you that the addition of the graphic icon accompanied by the website address "TreatMyHeartburn.com" may not appear on the 14-count inner "not for resale" carton labels.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

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