DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-032/S-003

GENERAL ADVICE

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

We also refer you to the approval letter dated April 2, 2009 for this supplemental new drug application. Please note that the supplemental application description in the third paragraph erroneously includes the statement "the addition of the statement "24 Hour Heartburn Blocker" to the outer carton labels". This request was withdrawn in your revised labeling submission dated March 19, 2009 and is not included in the approved labeling attached to the April 2, 2009 action letter. Subsequent to this letter, a replacement letter will be sent to remove this phrase. The action date will be unchanged, but the signature time will be one minute later to permit differentiation between the two letters.

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

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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