CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-032

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-032

Dexcel Pharma Technologies Limited
Attention: John D. Franolic, Ph.D.
Manager, Lachman Consultant Services, Inc
US Agent
1600 Stewart Ave
Westbury, NY 11590

Dear Dr. Franolic:

Please refer to your new drug application (NDA) dated February 8, 2006, received February 10, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for omeprazole 20 mg delayed-release tablets.

We acknowledge receipt of your 2006 submissions dated March 7 and 23, June 20, July 21, August 25 (2), September 1 (2), October 23, and November 7, 15, 17, and 30.

We have completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to address the following:

1. During a recent inspection of one [redacted] facility for this application, our field investigator issued a 483 Notice of Findings to the facility's representative. Satisfactory resolution of these deficiencies is required before this application may be approved. b(4)

2. During a recent inspection of one of the manufacturing facilities for this application, our field investigator verbally conveyed issues to the facility's representative requiring revision to specifications and analytical procedures. Our review of these revisions is required before this application may be approved.

In addition, it will be necessary for you to submit draft labeling revised as follows:

[redacted] b(4)

b(4)

4. Provide draft labeling including the carton label with *Drug Facts*, package insert, and blister card for all package sizes (SKUs).

These draft labels should include the agreed upon labeling revisions submitted in your November 30, 2006 submission.

New drug interaction warnings have been added to the prescription omeprazole products and are being considered for labeling of the omeprazole-containing nonprescription products. Any labeling changes to the OTC omeprazole products will affect the labeling for your product.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

When you respond to the above deficiencies, include a summary of worldwide experience, including all adverse events, on the safety of your formulation currently marketed outside the United States. Include an updated estimate of use for your drug marketed in other countries.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with the Division of Nonprescription Clinical Evaluation and the Division of Gastrointestinal Products to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call LCDR Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center of Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Joyce Korvick, MD
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center of 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/

Joyce Korvick
12/8/2006 03:22:30 PM

Andrea Segal
12/8/2006 03:26:16 PM