DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-032

Lachman Consultant Services, Inc
Attention: John D. Franolic, Ph.D.
Manager
US Agent for Dexcel Pharma Technologies Limited
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 pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("the Act") for omeprazole 20 mg delayed-release tablets.

We acknowledge receipt of your submissions dated December 18, 2006; April 4 and 16, and June 4, 2007.

Your submission of December 18, 2006, constituted a complete response to our December 8, 2006, action letter.

This NDA provides for the nonprescription use of omeprazole 20 mg delayed release tablets for the treatment of frequent heartburn.

We have completed our review of this application, as amended. It is **tentatively approved** under 21 CFR 314.105(a) for use as recommended in the agreed-upon enclosed labeling (the 14-, 28-, 42-count carton labels with Drug Facts, the 14-count inner carton label with Drug Facts, and the package insert submitted June 4, 2007, and the blister card backing submitted December 18, 2006). This determination is contingent upon information available to us at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of any new information that may come to our attention.

The listed drugs referenced in your application, Prilosec and Prilosec OTC of AstraZeneca, are subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
6,150,380	November 10, 2018
4,786,505*PED	October 20, 2007
4,853,230*PED	October 20, 2007

5,690,960	November 25, 2014
5,753,265	June 7, 2015
5,817,338	October 6, 2015
5,900,424	May 4, 2016
6,403,616	November 15, 2019
6,428,810	November 3, 2019
6147103	April 9, 2019
6166213	October 9, 2018
6166213*PED	April 9, 2019
6191148	October 9, 2018
6191148*PED	April 9, 2019

Your application contains certifications to each of the patents under section 505(b)(2)(A)(iv) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("Paragraph IV certifications"). Section 505(c)(3)(C) of the Act provides that approval of a new drug application submitted pursuant to section 505(b)(2) of the Act shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the paragraph IV certifications. This action must be taken prior to the expiration of forty-five days from the date the notice provided under section 505(b)(3) is received by the patent owner/approved application holder. You notified us that Dexcel Pharma Technologies Limited ("Dexcel") complied with the requirements of section 505(b)(3) of the Act. In addition, you have notified the Agency that the patent owner and/or approved application holder has initiated a patent infringement suit against Dexcel with respect to patent 4,853,230, patent 4,786,505, and patent 6,150,380 in the United States District Court for the District of Delaware (AstraZeneca AB, Aktiebolaget Hässle, KBI-E, Inc., KBI, Inc. and AstraZeneca LP vs. Dexcel, Ltd., Dexxon, Ltd., Dexcel Pharma Technologies, Ltd. and Dexcel Pharma Technologies [Civil Action Case No. 06-358]).[1]

Therefore, final approval cannot be granted until:

1. a. expiration of the 30-month period provided for in Section 505(c)(3)(C) beginning on the date of receipt of the 45-day notice required under Section 505(b)(3), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or

   b. the date the court decides[2] that the patent(s) is/are invalid or not infringed as described in section 505(c)(3)(C)(i), (ii), (iii,) or (iv) of the Act, or,

   c. the listed patent(s) has/have expired, and

2. we are assured there is no new information that would affect whether final approval should be granted.

[1] We note that Dexcel failed to timely advise the FDA that it was sued in response to its notice of Paragraph IV certification. We remind you that the Agency's regulations require that a "505(b)(2) applicant *shall* notify FDA *immediately* of the filing of any legal action filed within 45 days of receipt of the notice of [paragraph IV] certification" (21 CFR 314.107(f)(2))(emphasis added).

[2] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

At least 60 days prior to the date when approval can be granted, or when requested, you should submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. This information should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Failure to submit this amendment will prompt a review of the application that may result in rescission of the tentative approval letter.

Any significant change in the conditions outlined in this NDA requires our review before final approval may be granted.

Before we issue a final approval letter, this NDA is not deemed approved.

This drug product may not be marketed and may be considered misbranded without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. Per our letter dated December 8, 2006, we are waiving the pediatric study requirement for this application.

If you have any questions, call 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
Acting 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/

Andrea Segal
6/14/2007 03:06:26 PM

Joyce Korvick
6/14/2007 03:58:26 PM