

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-032

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Lachman Consultant Services, Inc
Attention: Mary Ann D'Esposito
Manager
US Agent for Dexcel Pharma Technologies Limited
1600 Stewart Ave
Westbury, NY 11590

Dear Ms. D'Esposito:

Please refer to your new drug application dated February 8, 2006, received February 10, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for omeprazole 20 mg delayed-release tablets.

We acknowledge receipt of your submissions dated July 19, 2007, September 24, October 4 and 5, 2007 and November 13 and 28, 2007.

The October 5, 2007 submission constituted a complete response to our June 14, 2007 action letter.

This new drug application provides for the use of omeprazole 20 mg delayed release tablets for the nonprescription the treatment of frequent heartburn in adults 18 years of age and older.

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.

LABELING

Submit final printed labeling 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 (14-, 28-, 42-count carton labels with Drug Facts submitted on November 28, 2007, the 14-count inner carton label with Drug Facts and the package insert submitted October 5, 2007, and the blister card backing submitted December 18, 2006), and must be in the Drug Facts format (21 CFR 201.66), where applicable.

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 22-032.” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

In addition, we request that you submit one copy of the introductory promotional materials you propose to use for this product to this division.

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

PROPRIETARY NAME

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.

PEDIATRIC RESEARCH EQUITY ACT (PREA)

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. This drug product is appropriately labeled for use in ages less than 18 years for this indication. Therefore, no additional pediatric studies are needed in this age group.

LETTERS TO HEALTH CARE PROFESSIONALS

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

NDA 22-032

Page 3

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

Enclosure

**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

12/4/2007 05:03:00 PM