DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-989/S-006

Daiichi Pharmaceutical Corporation
Attention: Kenneth Palmer, M.Sc.
Director, Marketed Support, Global Regulatory Affairs
11 Phillips Parkway
Montvale, New Jersey 07645-1810

Dear Mr. Palmer:

Please refer to your supplemental new drug application dated June 13, 2005, received June 14, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EVOXAC (cevimeline HCl) Capsules, 30 mg.

We acknowledge receipt of your submissions dated July 29 and December 8, 2005 (facsimile).

This "Changes Being Effected" supplemental new drug application provides for the addition of a Post Marketing Adverse Events subsection to the ADVERSE REACTIONS section, and deleting Yamanouchi Pharma Technologies, Inc. as the manufacturer.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 13, 2005 (package insert, immediate carton and container labels). However, it is also noted that as agreed to on December 8, 2005, the following will be implemented with the next printing:

1. The following language will be inserted in the label immediately prior to the Post-marketing Adverse Events section:

The following adverse reaction has been identified during post approval use of Evoxac. Because post marketing adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

2. The currently listed Post-marketing Adverse Events: cholecystitis will be revised as follows:

Post-marketing Adverse Events
Liver and Biliary System Disorders: cholecystitis.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Dermatology and Dental Products, and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Margo Owens, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}
Stanka Kukich, M.D.
Acting Division Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
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/

John Kelsey

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