DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-989/S-008

Daiichi-Sankyo Pharma Development, Inc.
Attention: Lawrence Akinsanmi, M.D., Ph.D.
Senior Director, Regulatory Affairs
399 Thornall Street, 10th Floor
Edison, NJ 08837

Dear Dr. Akinsanmi:

Please refer to your supplemental new drug application dated June 8, 2006, received June 9, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EVOXAC® (cevimeline HCl) Capsules.

We acknowledge receipt of your submission dated November 8, 2006.

This supplemental new drug application provides for a revised package insert containing the FDA requested wording from the approval letter dated December 13, 2005. The revisions include additional language regarding post-marketing reports of cholecystitis.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the attached enclosed labeling (text for package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-989/S-008**." Approval of this submission by FDA is not required before the labeling is used.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (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}

Susan Walker, M.D.
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for 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/

Susan Walker
12/8/2006 04:30:08 PM