DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022287/S-004 **SUPPLEMENT APPROVAL**

Takeda Global Research & Development Center, Inc.
Attention: Nancianne Knipfer, PhD, RAC
Associate Director, Regulatory Affairs
One Takeda Parkway
Deerfield, IL 60015

Dear Dr. Knipfer:

Please refer to your supplemental new drug application dated and received, January 20, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for KAPIDEX® (dexlansoprazole) 30/60mg Delayed Release Capsules for oral use.

We acknowledge receipt of your submissions dated January 20 and March 2, 2010.

This "Prior Approval" supplemental new drug application proposes:

- Additional information to the ADVERSE REACTIONS section (6.2) of the Full Prescribing Information.

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 enclosed, agreed-upon labeling text.

Within 14 days from the date of this letter, please amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format that includes the changes approved in this supplemental application.

If you have any questions, call Maureen Dewey, at (301) 796 - 0845.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director, Safety
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22287	SUPPL-4	TAKEDA PHARMACEUTICALS NORTH AMERICA INC	DEXLANSOPRAZOLE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOYCE A KORVICK
03/19/2010