DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022287/S-003 **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 on November 30, 2009, 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 November 30 and December 4, 2009, January 8, January 14, Jauary 21, and March 3, 2010.

This "Prior Approval" supplemental new drug application provides for a proprietary name change to your labeling and packaging materials.

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.

Also, we have the following comments:
On the hospital unit dose blister label, the RX only statement is more prominent than the product strength. At the time of your next printing, relocate the RX only statement so that it appears below the product strength. Additionally, debold and make the RX only statement smaller.

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.

Submit final printed carton and container labels for review as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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 Carton and Container Labels for approved NDA 022287/S-003." Approval of this submission by FDA is required before the labeling is used.

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 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
Carton and container packaging

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22287	SUPPL-3	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