



NDA 21-507/S-009

APPROVAL LETTER

Takeda Pharmaceuticals North America, Inc
Attention: Tonya Haynes, MPH, RAC
Product Manager, Regulatory Affairs
One Takeda Parkway
Deerfield, Illinois 60015

Dear Ms. Haynes:

Please refer to your supplemental new drug application dated October 1, 2008, received October 2, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid NapraPAC (lansoprazole delayed-release 15 mg capsules and naproxen 500 mg tablets kit).

We acknowledge receipt of your submissions dated March 4, 2009, March 26, 2009, and May 28, 2009. We also reference our emails to you on March 18, 2009, April 29, 2009, and July 15, 2009, containing labeling revisions.

This "Changes Being Effected" supplemental new drug application provides for revisions to the Description, Precautions, and Adverse Reactions sections of the package insert (PI), as well as other minor changes.

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 and with the minor editorial revisions listed below.

- Please ensure that the revision date states July 2009 (the month in which this label is approved).

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling and with the minor editorial revisions listed above. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-507."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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

REPORTING REQUIREMENTS

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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

Anne Pariser, M.D.
Acting Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

ANNE R PARISER
07/31/2009