



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-406/S-067
NDA 21-281/S-024
NDA 21-428/S-017

Takeda Pharmaceuticals North America, Inc.
Attention: Leslie Abelson
Assistant Director, Regulatory Affairs
675 North Field Avenue
Lake Forest, IL 60045

Dear Ms. Abelson:

Please refer to your supplemental new drug applications dated April 25, 2008, received April 28, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid (lansoprazole) Delayed-Release Capsules, Prevacid (lansoprazole) Delayed-Release Oral Suspension, and Prevacid SoluTab (lansoprazole) Delayed-Release Orally Disintegrating Tablets, 15 and 30 mg.

We acknowledge receipt of your submissions dated May 14, August 19, August 27 and September 9, 2008.

These supplemental new drug applications provide for the inclusion of information in the package insert regarding the use of Prevacid in patients less than one year of age with symptomatic GERD.

We completed our review of these applications, as amended. These supplements do not support the use of Prevacid in patients less than one year of age with symptomatic GERD. These applications are approved, effective on the date of this letter. However, the agreed-upon labeling changes reflect the lack of efficacy in this patient population.

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

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. 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 20-406/S-067, 21-281/S-024, and 21-428/S-017."

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 supplements NDA 20-406/S-067, 21-281/S-024, and 21-428/S-017.” Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division 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
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
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 Matthew Scherer, Regulatory Project Manager, at (301) 796-2307.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Director
Division of Gastroenterology 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/

Donna Griebel
10/28/2008 05:47:22 PM