



NDA 20-406/S-073  
NDA 21-428/S-020

**SUPPLEMENT APPROVAL**

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

Dear Ms. Haynes:

Please refer to your August 31, 2009, Supplemental New Drug Application (sNDA), received September 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prevacid (lansoprazole):

NDA	Supplement	Dosage Form
20-406	S-073	Delayed-Release Capsules
21-428	S-020	Delayed-Release Orally Disintegrating Tablets

We acknowledge receipt of your submission dated January 12, 2010, serving to withdraw your approval of NDA 21-281 Prevacid (lansoprazole) For Delayed-Release Oral Suspension. (b) (4)

These “Changes Being Effected” supplemental new drug applications provide for the following changes to the package insert (PI):

- Add statement in **Highlights, Use in Specific Populations** that Prevacid is not effective in patients with symptomatic GERD age 1 month to less than 1 year of age
- Move nasogastric tube administration information to a more prominent location in **Dosage and Administration**
- Add instruction to **Dosage and Administration** and **Patient Counseling Information** that Prevacid SoluTab delayed-release orally disintegrating tablets should not be broken or cut
- Remove reference to the oral suspension formulation

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling. For administrative purposes, please designate this submission, "SPL for approved NDA 20-406/S-073, NDA 21-428/S-020".

### **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 <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

### **LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related 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  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

NDA 20-406/S-073

NDA 21-428/S-020

Page 3

If you have any questions, call Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure: Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21428	SUPPL-20	TAKEDA PHARMACEUTICA LS NORTH AMERICA INC	PREVACID(LANSOPRAZOLE) 15/30 MG TABLETS
NDA-20406	SUPPL-73	TAKEDA PHARMACEUTICA LS NORTH AMERICA INC	PREVACID

---

**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  
05/12/2010