DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077255

TEVA Pharmaceuticals USA
Attention: Philip Erickson
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 27, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Lansoprazole Delayed-release Capsules USP, 15 mg and 30 mg.

Reference is made to our tentative approval letters dated January 18, and May 23, 2008. Reference is also made to your amendments dated January 31, 2005; March 2, 2006, December 30, 2008; and May 5, September 21, October 16, October 28, and November 5, 2009.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Lansoprazole Delayed-release Capsules USP, 15 mg and 30 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Prevacid Delayed-release Capsules, 15 mg and 30 mg, respectively, of Takeda Pharmaceuticals North America, Inc.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

Your "interim" dissolution testing should be conducted in the following manner:

Acid Stage:

Apparatus: USP Apparatus II (Paddle)
Speed: 75 rpm
Medium: 0.1 N HCl
Volume: 500 mL
Duration: 1 hour

Specification: NMT (b) (4) in 60 minutes

Buffer Stage:

Apparatus: USP Apparatus II (Paddle)
Speed: 75 rpm
Medium: phosphate buffer pH 6.8 with 5 mM SDS
Volume: 900 mL

Specification: NLT (b) (4) (Q) in 60 minutes

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" if there are no revisions to be made to these "interim" specifications or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The listed drug product (RLD) referenced in your application, Prevacid Delayed-release Capsules, 15 mg and 30 mg, of Takeda Pharmaceuticals North America, Inc. is subject to a period of patent protection. The following unexpired patent and its expiration date (with pediatric exclusivity extension) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book" for this drug product:

U.S. Patent Number	Expiration Date
5,013, 743 (the '743 patent)	August 12, 2010

With respect to the '743 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act indicating that this is a method of use patent, and that this patent does not claim any proposed indication for which you are seeking approval under your ANDA.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and 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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that

version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "***Miscellaneous Correspondence - SPL for Approved ANDA 077255***".

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-77255	ORIG-1	TEVA PHARMACEUTICALS USA	LANSOPRAZOLE

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

/s/

ROBERT L WEST
11/10/2009
Deputy Director, for Gary Buehler