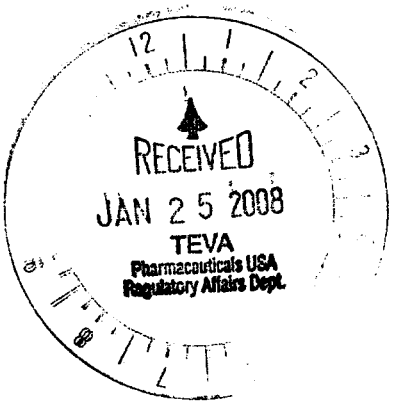
DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-793



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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated July 12, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Pravastatin Sodium Tablets, 80 mg.

Reference is also made to our tentative approval letter dated January 31, 2007, and to your amendments dated November 18, 2005; January 25, April 17, April 28, and September 8, 2006; and June 28, September 26, and December 18, 2007.

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 Pravastatin Sodium Tablets, 80 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Pravachol Tablets, 80 mg, of Bristol Myers Squibb (BMS). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, BMS's Pravachol Tablets, is subject to periods of patent protection. The following patents and their expiration dates (with pediatric exclusivity added) 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
5,030,447 (the '447 patent)	January 9, 2009
5,180,589 (the '589 patent)	January 9, 2009
5,622,985 (the '985 patent)	October 22, 2014

With respect to the '447 and '589 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Pravastatin Sodium Tablets, 80 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against TEVA Pharmaceuticals USA (TEVA) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. You have notified the agency that TEVA complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '447 or '589 patents was brought against TEVA within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to the '985 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that this is a method of use patent, and that your ANDA does not claim any indication that is protected by this patent.

In our tentative approval letter dated January 31, 2007, we were unable to grant final approval to your Pravastatin Sodium Tablets, 80 mg, because another ANDA providing for the 80 mg strength and containing paragraph IV certifications to the listed patents was submitted to the agency prior to the submission of your ANDA. Under section 505(j)(5)(B)(iv) of the Act, Ranbaxy Laboratories Limited's (Ranbaxy) ANDA was entitled to 180-day generic drug exclusivity for Pravastatin Sodium Tablets, 80 mg. This exclusivity expired on December 17, 2007.

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.

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.

Sincerely yours,

{See appended electronic signature page}

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

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
1/15/2008 12:03:23 PM
for Gary Buehler