DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-056

Food and Drug Administration
Rockville MD 20857

APR 24 2006

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 20, 2000, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Pravastatin Sodium Tablets, 10 mg, 20 mg, and 40 mg.

Reference is also made to the tentative approval letter issued by this office on May 15, 2002, and to your amendments dated December 7, 2005; and February 3, February 8, and April 3, 2006. We also acknowledge your correspondence dated August 5, 2002, and January 6, 2003, pertaining to patent and/or labeling exclusivity issues associated with this drug product as noted below.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved. The Division of Bioequivalence has determined your Pravastatin Sodium Tablets, 10 mg, 20 mg, and 40 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Pravachol Tablets, 10 mg, 20 mg, and 40 mg, respectively, of Bristol Myers Squibb. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

As discussed in our tentative approval letter, the reference listed drug (RLD) upon which you have based your ANDA, Pravachol Tablets of Bristol Myers Squibb, is subject to periods of patent protection. The following patents and 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
4,346,227 (the '227 patent)	April 20, 2006
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 '985 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act indicating that the '985 patent is a method of use patent, and that this patent does not claim any of the indications for which you are seeking approval.

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 these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of this drug product. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action was brought against TEVA Pharmaceuticals USA (TEVA) for infringement of one or more of the patents that were the subjects of the certifications. You have notified the FDA that TEVA complied with the requirements of section 505(j)(2)(B) of the Act and that no action for infringement of either 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 '227 patent, your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiration of the '227 patent. The '227 patent, with pediatric exclusivity added, expired on April 20, 2006.

With respect to 180-day generic drug exclusivity, the agency has concluded that TEVA was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '447 and '589 patents. Therefore, with this approval, TEVA is eligible for 180-days of generic drug exclusivity for Pravastatin Sodium Tablets, 10 mg, 20 mg, and 40 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act,[1] will begin to run from the earlier

[1] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv). Please submit correspondence to your ANDA informing the Agency of the date exclusivity begins to run.

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.

Post-marketing 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(s) 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 materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Robert L. Lest for

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