ANDA 76-341/S-001 & S-002

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 240-276-8474

FAX TRANSMISSION COVER SHEET

DATE: December 28, 2007

TO: Apotex Corp.,
U.S. Agent for Apotex Inc.

PHONE: 954-384-3986

ATTN: Kiran Krishnan

FAX: 954-349-4233

FROM: Jeanne Skanchy

PROJECT MANAGER: 240-276-8467

TOTAL NUMBER OF PAGES: 3
(EXCLUDING COVER SHEET)

Special Instructions:

Congratulations, your supplemental applications have been approved!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-341/S-001 & S-002

Apotex Corp.
Attention: Kiran Krishnan
U.S. Agent for Apotex Inc.
2400 N. Commerce Parkway, Suite 400
Weston, FL 33326

Dear Sir:

This is in reference to your supplemental new drug applications dated October 17, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Pravastatin Sodium Tablets USP, 10 mg, 20 mg, 40 mg, and 80 mg.

Reference is also made to our letter of October 23, 2006, which approved the 10 mg, 20 mg, and 40 mg strengths, and tentatively approved the 80 mg strength.

The supplemental applications, submitted as "Prior Approval Supplements," provide for the following changes:

S-001: Full approval for the 80 mg strength.

S-002: Labeling revision to reflect the changes.

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
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 is brought against Apotex Inc. (Apotex) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. You notified the agency that Apotex complied with the requirements of section 505(j)(2)(B) of the Act, and no action for infringement of either the '447 or '589 patents was brought against Apotex 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 that does not claim any indication for which you are seeking approval under your ANDA.

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved ANDA described in 21 CFR 314.80-81. The material submitted is being retained in our files.

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
12/28/2007 01:44:55 PM
for Gary Buehler