DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-048

Apotex Corp.
Attention: Tammy McIntire
2400 N. Commerce Parkway, Suite 400
Weston, FL 33326

Sent by Facsimile and U.S. Mail

Dear Ms. McIntire:

This is in reference to your abbreviated new drug application (ANDA) dated December 5, 2000, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Omeprazole Delayed-release Capsules, 10 mg, 20 mg, and 40 mg.[1]

Your ANDA was approved on October 6, 2003, because the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, had expired. The October 6, 2003 approval pertained to the 10 mg and 20 mg strengths only; the agency letter of October 6, 2003, tentatively approved the 40 mg strength. The statute anticipates that in some cases an ANDA may be approved before litigation concerning the listed patents is completed. Section 505(j)(5)(B)(iii). This leaves open the possibility that, as happened with these products, the approved drug products will later be found to infringe a listed patent.

As you know, on June 14, 2007, Judge Barbara Jones of the United States District Court for the Southern District of New York, issued a Judgment in *In re Omeprazole Patent Litigation*, M-21-81 (BSJ) that affects the status of your ANDA. The court ordered that "Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of approval for the aforementioned products and related ANDAs shall be not earlier than October 20, 2007, the date on which the six-month period of pediatric exclusivity under 21 U.S.C. § 355a(b)(2)(B) expires." See Judgment, *In re Omeprazole Patent Litigation*, M-21-81 (BSJ), at ¶ 3.

We are writing to inform you that, in light of this court order, the Agency hereby converts the final approval of ANDA 76-048 issued on October 6, 2003, to a tentative approval. Therefore, your ANDA is now **tentatively approved.** Final approval cannot be granted earlier than October 20, 2007.

[1] The reference listed drug (RLD) upon which you have based your ANDA, AstraZeneca's Prilosec Delayed-release Capsules, is subject to periods of patent protection and pediatric exclusivity. As noted in the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), the pediatric exclusivity periods of U.S. Patent Nos. 4,786,505 (the '505 patent) and 4,853,230 (the '230 patent) are scheduled to expire on October 20, 2007. The other patents listed in the Orange Book for Prilosec Delayed-release Capsules were not the subjects of litigation and therefore are not relevant to the action the Agency is taking in this letter.

Because the Agency is granting a tentative approval for this ANDA, when you believe that your ANDA may be considered for final approval, you must amend your ANDA to notify the Agency regarding whether circumstances have or have not arisen that may affect the effective date of final approval. To reactivate your ANDA, please submit an amendment at least 60 days (but not more than 90 days) prior to the date your ANDA will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final printed labeling, chemistry, manufacturing, and controls data as appropriate. Please note that this amendment should be submitted even if none of these changes were made. The amendment should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above. Any changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the ANDA will be made.

The drug products that are the subject of this ANDA may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery or introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 301(d) of the Act.

For further information regarding this issue, please contact Cecelia Parise, R.Ph., Regulatory Policy Advisor to the Director, Office of Generic Drugs, at (240) 276-9310.

Sincerely yours,

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

cc: Sheldon Bradshaw, Office of the Chief Counsel

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

/s/

Gary Buehler
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