DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-482

Apotex Corp.
U.S. Agent for Apotex Inc.
Attention: Kiran Krishnan
Associate Director, Regulatory Affairs
2400 North Commerce Parkway
Suite 400
Weston, FL 33326

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 27, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Eplerenone Tablets, 25 mg and 50 mg.

Reference is also made to your amendments dated April 16, May 10, and June 18, 2007; and February 8, February 14, February 22, March 7, July 4, and July 14, 2008.

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 Eplerenone Tablets, 25 mg and 50 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Inspra Tablets, 25 mg and 50 mg, of G.D. Searle LLC. (Searle). 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, Searle's Inspra Tablets, 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"):

U.S. Patent Number	Expiration Date
6,410,054 (the '054 patent)	June 8, 2020
6,410,524 (the '524 patent)	May 5, 2020
6,495,165 (the '165 patent)	June 8, 2020
6,534,093 (the '093 patent)	June 8, 2020
6,558,707 (the '707 patent)	June 8, 2020
6,747,020 (the '020 patent)	May 5, 2020
6,863,902 (the '902 patent)	October 10, 2020
7,157,101 (the '101 patent)	June 8, 2020

With respect to the '054, '524, '165, '093, '707, '902, and '101 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 Eplerenone Tablets, 25 mg and 50 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 have notified the agency that Apotex complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement 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 ‘524 (U-467 reference) and '020 patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act indicating that these are method of use patents, that do not claim any proposed indication for which you are seeking approval under your ANDA.

With respect to 180-day generic drug exclusivity, we note that Apotex was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '054, '524, '165, '093, '707, and '902 patents. Therefore, with this approval, Apotex is eligible for 180-days of generic drug exclusivity for Eplerenone Tablets, 25 mg and 50 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the 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.

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(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 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
7/30/2008 11:53:19 AM
Deputy Director, for Gary Buehler