DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 79-162

InvaGen Pharmaceuticals Inc.
Attention: Sudhakar R. Vidiyala
President
7 Oser Avenue
Hauppauge, NY 11788

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 10, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Topiramate Tablets, 25 mg, 50 mg, 100 mg and 200 mg.

Reference is also made to your amendments dated January 4, February 8, October 21, and December 4, 2008; and January 19, February 12, and March 26, 2009.

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 Topiramate Tablets, 25 mg, 50 mg, 100 mg and 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Topamax Tablets, 25 mg, 50 mg, 100 mg and 200 mg, respectively, of Ortho McNeil Janssen Pharmaceuticals, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The reference listed drug (RLD) upon which you have based your ANDA, Topamax Tablets of Ortho-McNeil Janssen Pharmaceuticals Inc., is subject to periods of patent protection. The following patents with their expiration dates (pediatric exclusivity extensions 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
5,998,380 (the '380 patent)	April 13, 2016
6,503,884 (the '884 patent)	April 13, 2016
7,018,983 (the '983 patent)	April 13, 2016
7,498,311 (the ‘311 patent)	April 13, 2016

With respect to each of these patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act that that these are method of use patents, and that these patents are not infringed by any indication for which you are seeking approval under this ANDA.

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.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "***Miscellaneous Correspondence - SPL for Approved ANDA 79-162***".

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
3/27/2009 02:43:31 PM
Deputy Director, for Gary Buehler