DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-448

Barr Laboratories, Inc.
Attention: Nicholas Tantillo
Sr. Director - Regulatory Affairs
225 Summit Avenue
Montvale, NJ 07645

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 28, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Topiramate Capsules (Sprinkle), 15 mg and 25 mg.

Reference is made to our tentative approval letter dated December 17, 2003. Reference is also made to your amendments dated October 31, 2005; December 22, 2008, March 9, 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 Capsules (Sprinkle), 15 mg and 25 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Topamax Sprinkle of Ortho McNeil Janssen Pharmaceuticals, Inc. (Ortho McNeil). 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, Ortho McNeil's Topamax Sprinkle, 15 mg and 25 mg, is subject to periods of patent protection. The following patents and expiration dates 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
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
7,125,560 (the '560 patent)	September 1, 2019
7,498,311 (the '311 patent)	April 13, 2016

With respect to the '380, '884, '983, and '311 patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act indicating that these are method of use patents, and that they do not claim any indication for which you are seeking approval under your ANDA.

With respect to the '560 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Topiramate Capsules (Sprinkle), 15 mg and 25 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 Barr Laboratories, Inc. (Barr) for infringement of the listed '560 patent. You have notified the agency that Barr complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Barr for infringement of the '560 patent in the United States District Court for the District of New Jersey [Ortho-McNeil Janssen Pharmaceuticals, Inc. v. Barr Laboratories, Inc., Civil Action No. 06-CV-06012]. You have also notified the agency that the case was dismissed; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

With respect to 180-day generic drug exclusivity, we note that Barr was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification to the '560 patent. Therefore, with this approval, Barr is eligible for 180 days of generic drug exclusivity for Topiramate Capsules, 15 mg and 25 mg, which will begin to run from the commercial marketing dates identified in section 505(j)(5)(B)(iv).[1] 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.

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 section 505-1(i) of the Act.

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

[1] This reference to the 180-day exclusivity provisions is to the section of the Act as in effect prior to enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003. The reasons for applying the pre-MMA 180-day exclusivity provisions to ANDAs for Topiramate Sprinkle Capsules are described in a letter being issued today under separate cover.

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.

You have been requested to provide information after the ANDA has been approved. Any information submitted to meet the conditions requested in this letter is considered a "Post Approval Commitment Response." To alert the Office of Generic Drug staff to the fact that you are providing post approval commitment information, please designate your submission in your cover letter as "POST APPROVAL COMMITMENT RESPONSE."

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 76-448".***

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/

Gary Buehler

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