



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

ANDA 77-868

Cobalt Laboratories Inc.  
Attention: Richard Sanzen  
Director, Regulatory Affairs  
Building B, Suite 1  
24840 S. Tamiami Trail  
Bonita Springs, FL 34134

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 6, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Topiramate Sprinkle Capsules, 15 mg and 25 mg.

Reference is also made to the tentative approval letter issued by this office dated May 13, 2008, and to your amendments dated February 27, and May 2, 2006; August 9, 2007; and December 23, 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 Topiramate Sprinkle Capsules, 15 mg and 25 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Topamax Sprinkle Capsules, 15 mg and 25 mg, of Ortho McNeil Pharmaceutical Inc. (Ortho McNeil).

The RLD upon which you have based your ANDA, Ortho McNeil's Topamax Sprinkle Capsules, 15 mg and 25 mg, 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

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 Sprinkle Capsules, 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 was brought against Cobalt Laboratories Inc. (Cobalt) for infringement of the listed '560 patent. You notified the agency that Cobalt complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Cobalt within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(2)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that Cobalt 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, Cobalt is eligible for 180 days of generic drug exclusivity for Topiramate Capsules, 15 mg and 25 mg, which will begin to run from the earlier of the court decision or commercial marketing dates identified in section 505(j)(5)(B)(iv) of the Act.<sup>1</sup> 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.

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<sup>1</sup> 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 today under separate cover.

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

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 77-868".**

Sincerely yours,

*{See appended electronic signature page}*

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

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

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Gary Buehler  
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