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APPLICATION NUMBER:

204412Orig1s000

APPROVAL LETTER



NDA 204412

NDA APPROVAL

Warner Chilcott Company, LLC
c/o Warner Chilcott (US), LLC
Attention: Wei Zhuang
Senior Manager, Regulatory Affairs
100 Enterprise Drive
Rockaway, NJ 07866

Dear Ms. Zhuang:

Please refer to your New Drug Application (NDA) dated July 31, 2012, received August 1, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Delzicol (mesalamine) Delayed-Release Capsules 400mg

We acknowledge receipt of your amendments dated August 7, 2012, September 7, 2012, September 14, 2012, September 18, 2012, September 25, 2012, September 26, 2012, October 3, 2012, October 16, 2012, November 1, 2012, November 16, 2012, November 27, 2012, December 14, 2012, December 17, 2012, December 18, 2012, December 19, 2012, January 2, 2013, January 7, 2013, January 9, 2013, January 11, 2013, January 16, 2013, January 18, 2013, January 22, 2013, January 29, 2013, January 30, 2013, and February 1, 2013.

This new drug application provides for the use of Delzicol (mesalamine) Delayed-Release Capsules 400 mg for treatment of mildly to moderately active ulcerative colitis and for maintenance of remission of ulcerative colitis.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE-CONTAINER LABELS

We acknowledge your January 29, 2013, submission containing final printed carton and container labels.

ADVISORY COMMITTEE

Your application for mesalamine was not referred to an FDA advisory committee because outside expertise was not necessary; there were no controversial issues that would benefit from advisory committee discussion.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to less than 5 years because necessary studies are impossible or highly impracticable. This is because there is a low incidence of ulcerative colitis in this age group.

We are deferring submission of your pediatric studies for ages 5 to 17 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. These required studies are listed below.

2011-1 A randomized, double-blind study in pediatric patients ages 5 to 17 years with ulcerative colitis using an age-appropriate formulation to evaluate the pharmacokinetics, safety, and clinical response of pediatric patients undergoing six weeks of oral mesalamine therapy. The study should compare at least two different dose levels of mesalamine and enroll at least 40 pediatric patients in each dosing arm.

Final Protocol Submission:	08/2013
Study/Trial Completion:	05/2015
Final Report Submission:	09/2015

2011-2 A randomized, double-blind study in pediatric patients ages 5 to 17 years using an age-appropriate formulation for the maintenance of remission of ulcerative colitis.

Final Protocol Submission: 08/2013
Study/Trial Completion: 05/2016
Final Report Submission: 09/2016

Submit the protocols to your IND 026093, with a cross-reference letter to this NDA.

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

2011-3 Collect additional dissolution profile data (including the additional 75 min timepoint, n=12) from the stability batches at the scheduled time points and from at least (b) (4) batches manufactured during the first year after action date. These data will be used for the setting of the final dissolution acceptance criteria.

Submit the final report with the complete dissolution information/data under a supplement to the NDA.

The timetable you submitted on January 4, 2013, states that you will conduct this study according to the following schedule:

Final Protocol Submission: NA
Study/Trial Completion: 02/2014
Final Report Submission: 05/2014

Submit clinical protocols to your IND 026093 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol,**"

“Postmarketing Commitment Final Report,” or “Postmarketing Commitment Correspondence.”

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call CDR Anissa Davis, Senior Regulatory Project Manager, at (301) 796-5016.

Sincerely,

{See appended electronic signature page}

Joyce A. Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn
Error Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling
Carton and Container Labeling

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

/s/

JOYCE A KORVICK
02/01/2013