CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-000

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-000

Shire Development, Inc.
Attention: Nurit Rojstaczer, Ph. D.
Manager, Regulatory Affairs
725 Chesterbrook Boulevard
Wayne, PA 19087

Dear Dr. Rojstaczer:

Please refer to your new drug application (NDA) dated December 21, 2005, received December 21, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lialda (mesalamine) Delayed Release Tablets, 1.2g.

We acknowledge receipt of your submissions dated February 3, March 22, April 20, April 27, May 19, May 31, June 5, July 10, July 18, July 21, August 8, August 11, August 15, August 21, August 29, August 30, September 5, September 7, September 21, October 3, October 6, October 27, and December 13, 2006, January 2 and January 15, 2007.

This new drug application provides for the use of Lialda (mesalamine) Delayed Release Tablets for the induction of remission in patients with active, mild to moderate ulcerative colitis. Safety and effectiveness of Lialda beyond 8 weeks has not been established.

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

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, and submitted labeling for the immediate container and carton labels submitted December 13, 2006. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 22-000.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric study plan within 120 days of the date of this approval letter.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

Deferred pediatric study under PREA for the treatment of ulcerative colitis in pediatric patients of all ages.

Final Report Submission: December, 2010

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments**".

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the 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 20705-1266

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 Kristen Everett, Regulatory Project Manager, at (301) 796-0453.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure – package insert

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

/s/

Brian Harvey
1/16/2007 04:06:00 PM