DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-775/S-001

Adolor Corporation
Attention: Linda G. Young, R.Ph., J.D.
Vice President, Regulatory Affairs
700 Pennsylvania Drive
Exton, PA 19341-1127

Dear Ms. Young:

Please refer to your supplemental new drug application (S-001) dated October 6, 2008, received October 7, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Entereg (alvimopan) Capsules, 12 mg.

Your supplemental new drug application proposes a modification to the Risk Evaluation and Mitigation Strategy (REMS) for Entereg that was approved on May 20, 2008. The approved REMS consists of a communication plan, elements to assure safe use, implementation system, and a timetable for assessments of the REMS.

On August 29, 2008, a teleconference was held between the Division of Gastroenterology Products (the Division) and Adolor to discuss the registration process necessary for hospitals to be able to provide Entereg to its patients. The Division and Adolor agreed that modifications to the hospital registration form were needed to lessen possible confusion and to assure safe use.

On October 6, 2008, you submitted a proposed modification to the approved REMS which included a revised hospital registration form. Your proposed changes to the registration form are as follows:

1. The DEA line was changed to "Hospital DEA #." The word "hospital" was added to clarify that it cannot be a physician's DEA number.
2. The "Hospital Identification Number" was changed to "Health Industry Number" and the asterisk indicating that this is a mandatory field was removed (i.e., this is no longer a mandatory field).
3. "Authorized Signatory" was added in front of the "Name" line and the "Middle Name" line removed.
4. An asterisk was added to the "Title" line (making this a mandatory field) with check boxes to identify the individual as a hospital pharmacist or representative of the hospital's Pharmacy and Therapeutics Committee.
5. "Office Phone" was changed to "Pharmacy Phone" and an asterisk was added (making this a mandatory field).
6. "Fax" was changed to "Pharmacy Fax" and an asterisk was added (making this a mandatory field). The pharmacy phone and fax numbers will assist the Sponsor in confirming the information on the phone.
7. The statement "See Important Safety Information" was bolded and the words "including the Boxed Warning on the reverse side" were added to the top paragraph of the first page of the form.
8. The footer information was moved from the front side to the reverse side of the form.

9. The Adolor logo was changed and updated.
10. A note was added to the bottom of the first page requesting a separate form for each ship site with an accompanying DEA number.

On December 3, 2008, you submitted an amendment to the proposed modification to the REMS which contained an additional hospital registration form specifically for use by Veterans Administration (VA) hospitals. The differences between the VA registration form and the form used by other hospitals are the following:

1. The form title is "VA Medical Center Registration Form" in place of "Hospital Registration Form;"
2. The lines for the "Health Industry Number" and for the sales representative email address are omitted.

We completed our review of this application containing the proposed modification to the REMS. Your proposed modifications, as incorporated in the REMS appended to this letter, are approved, effective on the date of this letter. The timetable for submission of assessments will remain the same as that approved on May 20, 2008, with the original approval of Entereg.

The requirements for assessments of an approved REMS under section 505-1(g)(3) include, in section 505-1(g)(3)(B) and (C), requirements for information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) [or 21 CFR 601.70] and including any updates to the status information since the annual report was prepared. Failure to comply with the REMS assessment provisions in 505-1(g) could result in enforcement action.

Prominently identify future amendments containing the REMS assessments or proposed modifications with the following wording in bold capital letters at the top of the first page of the submission:

NDA 21-775 REMS ASSESSEMENT
NEW SUPPLEMENT FOR NDA 21-775 REMS ASSESSMENT
PROPOSED REMS MODIFICATION

If you have any questions, call Matthew Scherer, Regulatory Project Manager, at (301) 796-2307.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Modified approved REMS

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

/s/

Joyce Korvick

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