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RESEARCH**

APPLICATION NUMBER:

21-775

OTHER REVIEW(S)

REGULATORY PROJECT MANAGER LABELING REVIEW (PHYSICIAN LABELING RULE)

Division of Gastroenterology Products

Application Number: NDA 21-775

Name of Drug: Entereg (alvimopan) Capsules

Applicant: Adolor Corporation

Material Reviewed:

Submission Date(s): 8/9/07

Receipt Date(s): 8/10/07

Submission Date of Structure Product Labeling (SPL): 8/9/07

Type of Labeling Reviewed: SPL

Background and Summary

This review provides a list of revisions for the proposed labeling that should be conveyed to the applicant. These comments are based on Title 21 of the Code of Federal Regulations (201.56 and 201.57), the preamble to the Final Rule, Guidance(s), and FDA recommendations to provide for labeling quality and consistency across review divisions. When a reference is not cited, consider these comments as recommendations only.

Review

The following issues/deficiencies have been identified in your proposed labeling.

Highlights Section:

- ~~_____~~
[See Indications and Usage]
- Insert "." following the adverse events reporting instructions.
- Revision Date must appear in bold type.

- Place the Revision Date at the end of the Highlights section.
[21 CFR 201.57(a)(15)]

Full Prescribing Information:

- If the Highlights and Table of Contents do not fit on one page, insert Table of Contents on page 2.
- Increase spacing between identifying numbers and headings and subheadings. Identifying numbers must be presented in bold and must precede headings and subheadings by at least two square em's (i.e., two squares the size of the letter "m" in 8-point type). [21 CFR 201.57 (d)(7)]
- 
[See 11 DESCRIPTION]

Recommendations

An advice letter will be issued requesting that the sponsor address the identified deficiencies/issues and re-submit labeling by April 16, 2008. This updated version of labeling will be used for further labeling discussions.

Matthew Scherer
Regulatory Project Manager

Supervisory Comment/Concurrence:

Julieann DuBeau, MSN, RN
Chief, Project Management Staff

Drafted: MCS/April 2, 2008
Revised/Initialed: JD/ 4-3-08
Finalized: MCS/ 4-4-08

CSO LABELING REVIEW OF PLR FORMAT

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

/s/

Matthew Scherer
4/4/2008 09:03:26 AM
CSO

Julieann DuBeau
4/4/2008 09:44:49 AM
CSO