

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
200582Orig1s000

STATISTICAL REVIEW(S)



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/Serial Number: NDA 200-582/ 0000

Drug Name: Topotecan injection, 4 mg/4 mL

Indication(s): Treatment of small cell lung cancer sensitive disease after failure of first-line chemotherapy

Applicant: Hospira Inc.

Date(s): Submission date: 29 October 2009
PDUFA due date: 29 August 2010
Review completion date: 14 July 2010

Review Priority: Standard

Biometrics Division: Division of Biometrics 5 (HFD-711)

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Concurring Reviewers: Shenghui Tang, Ph.D., Team Leader
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Keywords: 505(b)(2) application, referenced clinical studies, label comparison

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1. EXECUTIVE SUMMARY

This is a New Drug Application (NDA) 505 (b)(2) submission seeking the indication for Topotecan Injection, 4 mg/4 mL, as a treatment of small cell lung cancer sensitive disease after failure of first-line chemotherapy. The basis for this submission is Hycamtin[®] (topotecan hydrochloride) for Injection, NDA 20-671, held by GlaxoSmithKline.

This serves as a labeling review, comparing the applicant's proposed label with Hycamtin[®] product label for consistency on report of clinical studies.

1.1 Conclusions and Recommendations

There are no clinical data submitted in this 505 (b)(2) application. Referenced clinical studies for this application include 1 randomized comparative study and 3 single-arm studies in recurrent or progressive small cell lung cancer patients used in the NDA 20-671 application.

The proposed label section 14 on clinical studies is compared to Hycamtin[®] product label for discrepancies. One discrepancy is found (please see the primary findings section below). The sponsor will be asked to correct the discrepancy.

1.2 Brief Overview of Clinical Studies

Not applicable for this 505 (b)(2) application

1.3 Statistical Issues and Findings

Major Statistical issues:

Not applicable for this 505 (b)(2) application

Primary findings:

The numbers 26 and 19 in proposed label Table 4 are referring to number of patients evaluable for response duration. This should be clarified, as in Hycamtin[®] product label Table 8.

Both the applicant's proposed label and Hycamtin[®] product label of the section on clinical studies of small cell lung cancer are in the Appendix for reference.

4 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS)
immediately following this page

SIGNATURES/DISTRIBUTION LIST

Primary Statistical Reviewer: Chia-Wen Ko, Ph.D.
Date: 14 July 2010

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200582	ORIG-1	HOSPIRA INC	TOPOTECAN INJ

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/s/

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