CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-281

PHARMACOLOGY REVIEW(S)

PHARMACOLOGY/TOXICOLOGY REVIEW

NDA number: 22-281; capsules; a 505(b)(2) Rx-to-OTC switch for Zegerid OTC (20 mg)

Review number: 1
Sequence number/date/type of submission: SN000, March 20, 2008
Information to sponsor: Yes () No (x)
Sponsor and/or agent: Schering-Plough Healthcare products
Reviewer name: Wafa A. Harrouk, Ph.D.
Division name: Division of Non-Prescription Clinical Evaluation (DNCE), Office of Non-Prescription Products (ONP)
HFD #: 560
Review completion date: October 30, 2008

Drug:

Generic name: Zegerid
Chemical name: Omeprazole

Drug class: Proton pump inhibitor

Introduction and background: The sponsor is proposing an Rx-to-OTC switch for Zegerid OTC capsules. This NDA was discussed under PIND 74,284 with the sponsor on February 7, 2007. This 505(b)(2) NDA application for Zegerid OTC capsules will rely on the agency's previous finding of safety and effectiveness for Prilosec OTC including the nonclinical findings. This NDA consists of pharmacokinetic data to bridge to the existing findings for Prilosec OTC as well as other data to support the safety and efficacy of Zegerid OTC™ capsules.

Nonclinical safety issues relevant to clinical use: None

Overall conclusions and recommendations: The sponsor is referring to the findings of safety and efficacy of the prescription Zegerid capsules products (NDA 21-849) and the Prilosec OTC tablets (NDA 21-229). No further non-clinical testing is recommended. There are no pharmacology/toxicology issues at this time. The NDAs can be approved from a pharmacology/toxicology perspective.

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/s/

Wafa Harrouk
11/25/2008 02:02:21 PM
PHARMACOLOGIST

Paul Brown
11/26/2008 08:43:19 AM
PHARMACOLOGIST

Refer to CMC review for Methods Validation.

Mary R. Vienna

Mary R. Vienna, Regulatory Project Manager

Date: 12/08/08