CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022283Orig1s000

PHARMACOLOGY REVIEW(S)

PHARMACOLOGY/TOXICOLOGY FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: 22-283 **Applicant:** Schering-Plough HealthCare Products (SPHCP) **Stamp Date:** March 20, 2008

Drug Name: Zegerid OTC Powder **NDA Type:** 505(b)(2)

Background: NDA 22-283 is an Rx-to-OTC switch for Zegerid OTC powder. This NDA was discussed under pIND 74,284 with the sponsor on February 7, 2007. This 505(b)(2) application for Zegerid OTC Powder relies on the agency's previous finding of safety and effectiveness for Prilosec OTC including nonclinical data. This NDA consists of pharmacokinetic data to bridge to the existing database available for Prilosec OTC as well as other data to support the safety and efficacy of Zegerid OTC™ Powder to oral suspension.

On **initial** overview of the NDA application: There are no outstanding pharmacology/toxicology issues since the sponsor will be referring to data submitted under the Rx NDA.

	Content Parameter	Yes	No	Comment
1	On its face, is the pharmacology/toxicology section of the NDA organized (in accord with 21 CFR 314 and current guidelines for format and content) in a manner to allow substantive review to begin?			N/A
2	Is the pharmacology/toxicology section of the NDA indexed and paginated in a manner allowing substantive review to begin?			N/A
3	On its face, is the pharmacology/ toxicology section of the NDA legible so that substantive review can begin?			N/A
4	Are all required (*) and requested IND studies (in accord with 505 b1 and b2 including referenced literature) completed and submitted in this NDA (carcinogenicity, mutagenicity*, teratogenicity*, effects on fertility, juvenile studies, acute and repeat dose adult animal studies*, animal ADME studies, safety pharmacology, etc)?	x		
5	If the formulation to be marketed is different from the formulation used in the toxicology studies, have studies by the appropriate route been conducted with appropriate formulations? (For other than the oral route, some studies may be by routes different from the clinical route intentionally and by desire of the FDA).			N/A

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	Content Parameter	Yes	No	Comment
6	On its face, does the route of administration used in the animal studies appear to be the same as the intended human exposure route? If not, has the sponsor submitted a rationale to justify the alternative route?	x		
7	Has the sponsor submitted a statement(s) that all of the pivotal pharm/tox studies have been performed in accordance with the GLP regulations (21 CFR 58) or an explanation for any significant deviations?			N/A
8	Has the sponsor submitted all special studies/data requested by the Division during pre-submission discussions with the sponsor?			N/A
9	Are the proposed labeling sections relative to pharmacology/toxicology appropriate (including human dose multiples expressed in either mg/m2 or comparative serum/plasma levels) and in accordance with 201.57?			N/A
10	If there are any impurity – etc. issues, have these been addressed? (New toxicity studies may not be needed.)			N/A
11	Has the sponsor addressed any abuse potential issues in the submission?			N/A
12	If this NDA is to support a Rx to OTC switch, have all relevant studies been submitted?	x		
13	From a pharmacology/toxicology perspective, is the NDA fileable? If ``no`` please state below why it is not.	x		

Wafa Harrouk — April 23, 2008

Reviewing Pharmacologist — Date

Paul Brown — April 23, 2008

Team Leader/Supervisor — Date

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

/s/

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5/6/2008 04:57:40 PM
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