

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-881

**CLINICAL PHARMACOLOGY AND
BIOPHARMACEUTICS REVIEW(S)**

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		Clinical Pharmacology & Biopharmaceutics (HFD 870) Tracking/Action Sheet for Formal/Informal Consults		
From: Tien-Mien Chen, Ph.D. (HFD-870)		To: DOCUMENT ROOM (LOG-IN and LOG-OUT) Please log-in this consult and review action for the specified IND/NDA submission		
DATE: 03-23-06	IND No.: Serial No.:	NDA No. 210881	DATE OF DOCUMENT 06/07/05	
NAME OF DRUG PEG3350	PRIORITY CONSIDERATION S		Date of informal/Formal Consult: 09/14/05	
NAME OF THE SPONSOR: [Norgine B. V.]				
TYPE OF SUBMISSION				
CLINICAL PHARMACOLOGY/BIOPHARMACEUTICS RELATED ISSUE				
<input type="checkbox"/> PRE-IND	<input type="checkbox"/> ANIMAL to HUMAN SCALING	<input type="checkbox"/> IN-VITRO METABOLISM	<input type="checkbox"/> PROTOCOL	<input type="checkbox"/> PHASE II PROTOCOL
<input type="checkbox"/> PHASE III PROTOCOL	<input type="checkbox"/> DOSING REGIMEN CONSULT	<input type="checkbox"/> PK/PD- POPPK ISSUES	<input type="checkbox"/> PHASE IV RELATED	<input type="checkbox"/> DISSOLUTION/IN-VITRO RELEASE
<input type="checkbox"/> BIOAVAILABILITY STUDIES	<input type="checkbox"/> IN-VIVO WAIVER REQUEST	<input type="checkbox"/> SUPAC RELATED	<input type="checkbox"/> CMC RELATED	<input type="checkbox"/> PROGRESS REPORT
<input type="checkbox"/> SCIENTIFIC INVESTIGATIONS	<input type="checkbox"/> MEETING PACKAGE (EOP2/Pre-NDA/CMC/Pharmacometrics/Others)	<input type="checkbox"/> FINAL PRINTED LABELING	<input checked="" type="checkbox"/> LABELING REVISION	<input type="checkbox"/> CORRESPONDENCE
<input type="checkbox"/> DRUG ADVERTISING	<input type="checkbox"/> ADVERSE REACTION REPORT	<input type="checkbox"/> ANNUAL REPORTS	<input type="checkbox"/> FAX SUBMISSION	<input type="checkbox"/> OTHER (SPECIFY BELOW):
				[]
REVIEW ACTION				
<input type="checkbox"/> NAI (No action indicated)	<input type="checkbox"/> E-mail comments to:	<input type="checkbox"/> Medical <input type="checkbox"/> Chemist <input type="checkbox"/> Pharm-Tox	<input type="checkbox"/> Micro <input type="checkbox"/> Pharmacometrics <input type="checkbox"/> Others	(Check as appropriate and attach e-mail)
<input type="checkbox"/> Oral communication with	Name: []	<input checked="" type="checkbox"/> Comments communicated in meeting/Telecon. see meeting minutes dated: [labeling meeting on 03/23/06]	<input type="checkbox"/> Formal Review/Memo (attached)	<input type="checkbox"/> See comments below
<input type="checkbox"/> See submission cover letter	<input type="checkbox"/> OTHER (SPECIFY BELOW):			[]
REVIEW COMMENT(S)				
<input checked="" type="checkbox"/> NEED TO BE COMMUNICATED TO THE SPONSOR		<input type="checkbox"/> HAVE BEEN COMMUNICATED TO THE SPONSOR		
COMMENTS/SPECIAL INSTRUCTIONS:				
<p>[X] NDA 21-881 for PEG 3350 submitted on 06/07/05 was filed. It is for the indication of bowel cleansing prior to colonoscopy, _____ . Two pivotal clinical studies were conducted, but no human PK studies were done. Therefore, no formal review of this NDA by OCP reviewer is done. As concluded by the reviewing chemists in GI division, this NDA for bowel cleansing preparation prior to GI examination using PEG 3350 and electrolytes plus Vitamin C is considered as a combination drug product application. Further, no additional PK studies were needed to address the combination drug issues since PEG 3350 is known to act locally within the GI lumen and is minimally absorbed into systemic circulation and Vitamin C is not considered as a drug. No "Pharmacokinetics" subsection was proposed under "Clinical Pharmacology" section in the labeling. During the labeling meeting on 03/26/06, the following labeling comment was added and it was accepted by the sponsor:</p> <p>"The pharmacokinetics of MOVIPREP[®] in patients with hepatic or renal impairment have not been studied."</p>				
SIGNATURE OF REVIEWER: <u>Tien-Mien Chen, Ph.D.</u>			Date <u>03/23/06</u>	
SIGNATURE OF TEAM LEADER: <u>Edward D. Bashaw, Pharm. D.</u>			Date <u>03/23/06</u>	
CC.: HFD # [180]; TL: [EDB]			Project Manager: <u>T. Clayton</u> Date <u>03/23/06</u>	

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

/s/

Tien-Mien Chen
4/3/2006 02:06:46 PM
BIOPHARMACEUTICS

Dennis Bashaw
4/3/2006 03:15:50 PM
BIOPHARMACEUTICS

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