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APPLICATION NUMBER:

21-759

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW

NDA 21-759

Drug:	Eloxatin
Generic Name:	Oxaliplatin
Formulation:	Aqueous solution containing 50 or 100 mg of oxaliplatin for IV infusion.
Indication:	ELOXATIN, used in combination with infusional 5-FU/LV, is indicated for the treatment of advanced carcinoma of the colon and rectum
Applicant:	Sanofi-Synthelabo Inc.
OCPB Division:	Division of Pharmaceutical Evaluation I (HFD-860)
OND Division:	Division of Oncology Drug Products (HFD-150)
Submission Dates:	03/31/2004
Primary Reviewer:	Angela Yuxin Men, MD., Ph.D.
Acting Team Leader:	Brian Booth, Ph.D.
Type of Submission:	NDA-Original

Executive Summary

The applicant submitted the original NDA 21-759, seeking approval of an aqueous solution for ELOXATIN, in addition to the FDA-approved lyophilized ELOXATIN (NDA 21-492) to treat patients with advanced carcinoma of the colon and rectum in combination with infusional 5-FU/LV therapy.

The active ingredient, oxaliplatin, is the same for both formulations and it is supplied as 50 mg and 100 mg dosage strengths. The contents of these formulations are listed in Table 1. In the proposed solution formulation, oxaliplatin is dissolved in water [redacted] Oxaliplatin may then be further diluted in 5% dextrose. [redacted] No additional clinical data was submitted in NDA 21-759.

Table 1 Contents of Oxaliplatin Formulations

	Oxaliplatin Solution Formulation		Oxaliplatin Lyophilized Formulation	
Contents	**50 mg**	**100 mg**	**50 mg**	**100 mg**
Oxaliplatin	50 mg	100 mg	50 mg	100 mg
Water q.s.				
Reconstition[2]	Not applicable	Not applicable	10 mL water or D5W	20 mL water or D5W
Dilution[2]				

[2]Water for Injection (USP) or 5% Dextrose Injection (D5W).

Recommendation

The change in formulation is acceptable to Office of Clinical Pharmacology and Biopharmaceutics.

Angela Yuxin Men, MD, Ph.D.
Pharmacokinetic Reviewer
Division of Pharmaceutical Evaluation I

Brian Booth, Ph.D.
Acting Team Leader, Oncology
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CC: NDA 21-759
HFD-150/Division File
HFD-150/CCottrell, NChidambaram, HSarker
HFD-860/MMehta, NRahman, BBooth, AMen

CDR/Biopharm

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/s/

Angela Men
6/1/04 03:12:25 PM
BIOPHARMACEUTICS

Brian Booth
6/2/04 05:08:18 PM
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