CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206968Orig1s000

CLINICAL PHARMACOLOGY REVIEW(S)

CLINICAL PHARMACOLOGY REVIEW

NDA: 206968	Submission Date(s): 5/13/2014
Brand Name	Acetaminophen Injection
Generic Name	Acetaminophen Injection
Clinical Pharmacology Reviewer	Srikanth C. Nallani, Ph.D.
Team Leader	Yun Xu, Ph.D.
OCP Division	Division of Clinical Pharmacology II
OND Division	Anesthesia, Analgesia and Addiction Products
Sponsor	Innopharma, Inc.
Relevant IND(s)	NA
Submission Type	505(b)(2)
Formulation; Strength(s)	10 mg/mL
Indication	Relief of pain and fever.
Proposed Dosage Regimen	Administered every 4 – 6 hours.

Innopharma Inc. submitted a 505(b)(2) NDA application for approval of acetaminophen injection 10 mg/mL with reference to safety and efficacy established previously in an approved NDA 022450 Ofirmev (Reference Drug). There is no Clinical Pharmacology Data in the NDA. The proposed solution formation has the same active ingredient (acetaminophen), concentration (10 mg/mL), and intended route of administration (IV) as the Reference drug. The proposed unique acetaminophen formulation is packaged in 100 mL bags and intended to be therapeutically equivalent to Ofirmev.

Table: Comparison of proposed product to reference drug Ofirmev.

Ofirmev (acetaminophen injection, solution)			**InnoPharma's Acetaminophen Injection, 10 mg/mL**		
Ingredient	**Per Vial**	**Per mL**	**Ingredient**	**Per Bag**	**Per mL**
Acetaminophen	1000 mg	10 mg	Acetaminophen*	1000 mg	10.0 mg
Mannitol, USP	3850 mg	38.5 mg	Citric acid Anhydrous, USP	(b) (4)	
Cysteine hydrochloride monohydrate, USP	25 mg	0.25 mg	Sodium Chloride, USP		
Dibasic sodium phosphate, USP	10.4 mg	0.104 mg	Hydrochloric acid	As required to adjust pH to 5.5	
Hydrochloric acid	As required to adjust pH to 5.5		Sodium hydroxide	As required to adjust pH to 5.5	
Sodium hydroxide	As required to adjust pH to 5.5		Water for injection, USP	Quantity Sufficient	
Water	Quantity Sufficient				

The sponsor has submitted biowaiver request in the NDA as a follow up to the Pre-IND meeting. Dr. Kareen Riviere has reviewed the request and agreed to grant the biowaiver for this IV product (See review dated 1-5-2015).

Labeling: The proposed product label is identical to Ofirmev product label. It is noteworthy that Ofirmev product label was recently updated.

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/s/

SRIKANTH C NALLANI
02/03/2015

YUN XU
02/03/2015