OFFICE OF CLINICAL PHARMACOLOGY REVIEW

NDA: 20239	Submission Dates: March 30, 2010
Brand Name	Kytril
Generic Name	Granisetron HCl
Reviewers	PeiFan Bai, Ph.D.
Team Leader	Sue-Chih Lee, Ph.D.
OCP Division	Division of Clinical Pharmacology 3
OND Division	Division of Gastroenterology Products
Sponsor	Roche
Submission Type; Code	Pediatric Efficacy Supplement; S-023
Formulation; Strength(s)	IV injection; 1mg/ml (free base)l 0.1 mg/ml (free base)
Indication	Prevention of post-operative nausea and vomiting
Dosing Regimen	Recommended dosage is 1 mg, undiluted, administered intravenously over 30 seconds, before anesthetic induction or immediately before reversal of anesthesia.

SUMMARY

In a July 22, 2009 letter, the Agency requested Hoffmann-La Roche Inc. ("Roche") to submit an Efficacy Supplement for a Kytril pediatric post marketing commitment study. In response to that request, the sponsor submitted this Efficacy Supplement along with the revised Kytril labeling. The study submitted is a clinical trial to study the efficacy of Kytril Injection in the prevention of PONV in pediatric patients 2 to 16 years of age. There is no clinical pharmacology study or related new data submitted to this Efficacy Supplement except the revised Kytril labeling which is revised to meet the new label format requirement and to include new clinical efficacy data in pediatric patients. By reviewing the clinical pharmacology related sections in the revised and approved versions of Kytril labeling, it is concluded that the revised labeling is acceptable.

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/s/

PEIFAN J BAI
12/16/2010

SUE CHIH H LEE
12/16/2010