

## OFFICE OF CLINICAL PHARMACOLOGY REVIEW

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NDA: 20-845 (S-011)	Submission Date: June 24, 2010
Brand Name	INOMAX
Generic Name	Nitric Oxide for Inhalation
Reviewer	Partha Roy, Ph.D.
Team Leader (Acting)	Yun Xu, Ph.D.
OCP Division	Clinical Pharmacology 2
OND Division	Pulmonary, Allergy & Rheumatology Products
Sponsor	INO Therapeutics
Submission Type	Efficacy Supplement
Dosage Form	Gas for Inhalation
Current Indication	treatment of term and near-term (> 34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, where it improves oxygenation and reduces the need for extracorporeal membrane oxygenation

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This is an efficacy supplement with clinical data. There is no new clinical pharmacology information submitted. Hence there is no Clinical Pharmacology review for this supplement.

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/s/  
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PARTHA ROY  
11/19/2010

YUN XU  
11/19/2010