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APPLICATION NUMBER:

208223Orig1s000

PHARMACOLOGY REVIEW(S)

**Memorandum to File
Pharmacology/Toxicology, Division of Neurology Products (HFD-120)**

NDA: 208-223	Sponsor: Dr. Reddy's Laboratories, Ltd.
Drug: Sumatriptan Injection	Indication: Acute migraine

Subject: Nonclinical Data Requirements for NDABackground

NDA 208-223 was received on March 30, 2015, following development under IND 118,668 (May Proceed Letter, May 27, 2014). The application was filed as a 505(b)(2) NDA, relying on previous findings of sumatriptan safety and efficacy under NDA 20-080 (Imitrex Injection). A Pre-NDA meeting was held with the Sponsor on February 25, 2015 (Meeting Minutes, March 25, 2015). At that time the Sponsor was advised that, "No additional nonclinical studies will be required to support a 505(b)(2) NDA unless safety issues arise (e.g., impurities, leachables/extractables) that require nonclinical assessment."

Submission Contents

NDA 208-223 contains no nonclinical data.

Evaluation and Recommendations

The OPQ Reviewer, Dr. Sherita McLamore-Hines, has identified no drug product quality issues that raise safety concerns requiring nonclinical assessment. Therefore, no nonclinical data are required to support approval of the NDA.

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/s/

DONALD C THOMPSON
12/07/2015

LOIS M FREED
12/08/2015

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/s/

ROBYN S JORDON
07/05/2016