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APPLICATION NUMBER:

205703Orig1s000

SUMMARY REVIEW

DIVISION OF CARDIOVASCULAR & RENAL PRODUCTS

Divisional Memo

NDA: 205703 Esmolol

Sponsor: HQ Specialty Pharma

Review date: 7 April 2016

Reviewer: N. Stockbridge, M.D., Ph.D., HFD-110

Distribution: NDA 205703

This memo conveys the Division's recommendation to issue an Approval letter for this application.

This 505(b)(2) application received a tentative Approval on 14 April 2014, pending expiration of patent protection by the innovator product.

Labeling now reflects current practice.

There was then and are now no post-marketing requirements or commitments.

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/s/

NORMAN L STOCKBRIDGE
04/07/2016

DIVISION OF CARDIOVASCULAR & RENAL PRODUCTS

Divisional Memo

NDA: 205703 Esmolol

Sponsor: HQ Specialty Pharma

Review date: 12 April 2014

Reviewer: N. Stockbridge, M.D., Ph.D., HFD-110

Distribution: NDA 205703

This memo conveys the Division's recommendation to issue a Tentative Approval letter for this application.

This application has been the subject of reviews of CMC (Chu; 26 February 2014), microbiology (Miller; 26 February 2014), pharmacology/toxicology (Gatti; 3 September 2013), and biopharmaceutics (Houda; 20 March 2014)). There is a comprehensive CDTL memo (Srinivasachar; 4 April 2014) with which I am in full agreement. I highlight a few matters here.

This is a 505(b)(2) application by virtue of a formulation difference with the reference listed drug .

There are no CMC issues. Facility inspections are complete. The product will have a shelf-life of 18 months for the 2500-mg/250-mL formulation and 24 months for the 2000-mg/100-mL formulation.

Because of a pending patent infringement suit, the action will be a tentative approval. There are no post-marketing commitments or requirements.

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/s/

NORMAN L STOCKBRIDGE
04/12/2014