Clinical Memo
Division of Hematology Products

NDA:	NDA 207027/SD-006
Drug Name:	Promacta (eltrombopag) for oral suspension
Sponsor:	Novartis Pharmaceuticals
Date Received:	March 30, 2018
Reviewer:	Hyon-Zu Lee, Pharm.D.
Team Leader:	Kathy Robie-Suh, M.D., Ph.D.

Eltrombopag is a thrombopoietin receptor agonist approved initially on November 20, 2008 under NDA 22291 for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. On August 24, 2015, an oral suspension dosage form was approved for eltrombopag under NDA 207027 and the above indication was expanded to include pediatric patients ≥1 years of age. With the approval, the applicant agreed on the following Postmarketing Commitment:

”2948-1 Develop a 12.5 mg strength to provide for an additional dosing for patients needing less than the current lowest dose option of 25 mg. The timetable you submitted on August 20, 2015, states that you will conduct this study according to the following schedule:

Development Plan Submission: 12/2015
Development Study/Trial Completion: 12/2017
Final Report/Supplement Submission: 03/2018”

The current prior approval supplement contains CMC information and proposed labeling revisions to support the new dose strength (12.5 mg) for Promacta for oral suspension (PfOS). The submission also provides for marketing of the new 12.5 mg strength oral suspension in kits containing 30 packets and 30 single-use oral dosing syringes. The proposed labeling includes language to indicate that each oral dosing syringe is to be used only once. The language is acceptable. No clinical information was submitted in this supplement.

Conclusion and Recommendation:
From a clinical perspective, the supplement may be approved with the agreed upon labeling.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

HYON-ZU LEE
08/28/2018

KATHY M ROBIE SUH
08/28/2018