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APPLICATION NUMBER:

208325Orig1s000

OFFICE DIRECTOR MEMO

Summary Basis for Regulatory Action

Date	February 7, 2017
From	Curtis J. Rosebraugh, MD, MPH Director, Office of Drug Evaluation II
Subject	Summary Review
NDA/BLA #	208325
Supp #	
Applicant Name	Amgen
Proprietary / Established (USAN) Names	Parsabiv etelcalcetide
Dosage Forms / Strength	Single-use vials of solution for intravenous (IV) administration 5 mg/ mL Proposed starting dose: 5 mg injection three times a week to a maximum dose of 15 mg three times a week.
Proposed Indication(s)	Secondary hyperparathyroidism in patients with chronic kidney disease on hemodialysis
Action:	<i>Approval</i>

This review will be a brief summary of the basis for the regulatory action regarding etelcalcetide and I refer the reader to the reviews from the first cycle. During that review period I concluded that etelcalcetide had demonstrated safety and efficacy allowing for approval with appropriate labeling (please see my first review for a detailed discussion).

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 This was not appropriate (b) (4)

Subsequently, the sponsor has agreed to (b) (4) and (b) (4) (b) (4) etelcalcetide can be approved.

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/s/

CURTIS J ROSEBRAUGH
02/07/2017