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APPLICATION NUMBER:

204734Orig1s000

SUMMARY REVIEW

Divisional memo

NDA #	204734, Class 1 resubmission
Date	September 24, 2014
From	Norman Stockbridge, M.D., Ph.D.
Applicant	Shire Development LLC
Propriety name/ Established (USAN) name	Fosrenol oral powder / lanthanum carbonate powder
Dosage form / strength	(b) (4) / 750 and 1000 mg
Proposed indication	To reduce serum phosphate in patients with end stage renal disease (ESRD)

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

This application has been the subject of the following reviews.

CMC (Lyudmila Soldatova, 10/10/2013)
Biopharmaceutics (Okpo Eradiri, 10/25/2013, 12/20/2013)
Clinical pharmacology (Divya Menon-Andersen, 10/28/2013)
Clinical (Melanie Blank, 10/28/2013)
OSE/OMEPRM (Kimberley DeFronzo, 10/07/2013)
CDTL (Divya Menon-Andersen, 12/21/2013)

A complete response letter was issued on December 24, 2013. The reason for the action was the applicant's inability to develop and implement an adequate discriminatory dissolution testing method. It is useful to note that the applicant was of the position that such testing was unnecessary for a product formulated as (b) (4) for most of the review cycle, giving the Division little time to negotiate a path forward.

In response to the Complete Response letter the applicant proposed developing and implementing a dissolution testing method as a Postmarketing Commitment and utilizing (b) (4) dissolution specifications in the interim (sponsor's resubmission dated 31 July 2014). This was found acceptable by Biopharmaceutics (Okpo; review of 8 September 2014). Hence, following resolution of the sole issue preventing approval in the first cycle, the Division approves Fosrenol (lanthanum carbonate) oral powder for reduction of serum phosphate in patients with end stage renal disease (ESRD).

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/s/

NORMAN L STOCKBRIDGE
09/24/2014