

From: Levi, Mark  
Sent: Monday, 23 July, 2018 19.44  
To: 'barbara.rangetiner@octapharma.com'; Gorsche, Rita  
Cc: 'Ammons, Stanley'  
Subject: FDA IR for BL 125587

Sensitivity: Confidential

Dear Dr. Rangetiner,

Your full waiver request ( 0- less than 18 years of age) for the indication of ITP has been declined by pediatric review committee. However, a partial waiver has been granted for ages 0-1 years.

Please provide us with following time-line for your pediatric study in subjects >1 year and <18 years. This study will be required as post marketing study under PREA (Pediatric Research Equity Act).

Draft protocol submission  
Final protocol submission  
Study completion  
Final report submission

Please confirm receipt and reply by the end of Wednesday 25 July 2018.

Regards, Mark Levi  
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