

Rana, Pratibha

From: Rana, Pratibha
Sent: Tuesday, December 21, 2010 4:31 PM
To: 'Matthew Vaughn'
Subject: STN 125389/0 Information Request

Dear Matt,

This is regarding your BLA submission STN 125389/0 for Immune Globulin Intravenous (Human), submitted to the Agency on November 3, 2010. FDA continues with the review of the referenced submission and requests BPC to provide the following information.

1. Please submit pediatric waiver/deferral to the BLA. Please request a waiver for < 2 years and a deferral for 2 to 16 years. and provide a reason for the waiver and deferral.

For the deferral group, also submit a pediatric plan with the type of study, the date it will begin and the date it will be completed. The study should include PK, safety and efficacy. Generally these studies have had 20 subjects with the numbers spread evenly across the 2 to 16 year ages.

Thank you.

Pratibha Rana

Pratibha Rana, M.S.
Regulatory Project Manager

FDA/CBER/OBRR
Division of Blood Applications
1401 Rockville Pike
Rockville, MD 20852
Office: (301) 827-6124
Fax: (301) 827-2857
email: pratibha.rana@fda.hhs.gov

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