

From: Maruna, Thomas
Sent: Thursday, February 11, 2016 2:57 PM
To: 'Denloye, Aderonke O'
Subject: February 11. 2016 Information Request - BLA 125596.0 - Please Respond by February 17. 2016

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
February 11, 2016
Sent by email

Dear Ms. Denloye:

We are reviewing your September 14, 2015 biologics license application (BLA) to treat primary immune deficiency disorders associated with defects in humoral immunity for the following:

STN	Name of Biological Products
125596/0	Immune Globulin Subcutaneous (Human), 20% Solution

We have determined the following information is required to continue our review:

1. Please submit a pediatric assessment that contains data to support the safety and efficacy of Cuvitru for use in pediatric patients. Under PREA, the pediatric assessment should contain data gathered from pediatric studies that are adequate to assess the safety and effectiveness for the claimed indications in the following pediatric subpopulations:
 - a. 0 to <2 years,
 - b. ≥ 2 years to <6 years,
 - c. ≥ 6 years to <12 years,
 - d. ≥ 12 years to <16 years of age

The assessment should also summarize the number of Centers where pediatric subjects were enrolled, the number and names of countries they were enrolled in, the number of patients studied in each population, a summary of inclusion/exclusion criteria if different than for adults, statistical analysis performed, and the timing of assessments.

Please submit your responses to question 1 as an amendment to this file by February 17, 2016 referencing the date of this request.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

The action due date for these files is September 13, 2016.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH

Lieutenant, U.S. Public Health Service

Senior Regulatory Management Officer

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Blood Research and Review

10903 New Hampshire Ave.

Silver Spring, MD 20993

thomas.maruna@fda.hhs.gov

O: (240) 402-8454

www.usphs.gov



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