

Filing Meeting Summary

Date: October 29, 2015

Held by Email

From: LT Thomas J. Maruna, USPHS, MSc, MLS(ASCP)^{CM}

To: STN 125596/0

Re: Filing Meeting for Baxalta's Immune Globulin Subcutaneous (Human), 20% Solution

This meeting was held virtually in lieu of a face-to-face meeting. All review disciplines provided to the RPM a filing checklist, decision and comments in advance of the October 29, 2015 scheduled meeting; therefore, the scheduled face-to-face meeting was cancelled and each reviewer's notes are captured in this summary.

CBER Participants:

Review Committee	Discipline	Acceptable for Filing?
Reed, Jennifer	Chair/CMC	Yes
Struble, Evi	Pharmacology/Toxicology	Yes
Alimchandani, Meghna	Epidemiology	Yes
Campbell, Karen	DBSQC	Yes
Wernly, Claire		Yes
Wang, Hsiaoling (Charlene)		Yes
King, Colonious	Bioresearch Monitoring	Yes
Lorenzo, Anthony	DMPQ	Yes
Mahmood, Iftexhar	Clinical Pharmacology	Yes
Maruna, Thomas J.	Regulatory Management	Yes
Popat, Alpita	APLB	Yes
Storch, Emily	Clinical	Yes
Zaslavsky, Boris	Statistics	Yes

Background:

Baxalta US Inc. has submitted to the FDA for review an original Biologics License Application (BLA), STN 125596/0. This BLA arrived to the Agency on September 14, 2015. This application will be reviewed under a standard 10-month review schedule. The cross-reference to Investigational New Drug (IND) application is IND 14505; relevant pre-application meetings are as follows: CRMTS 7564, 9588 and 9715.

Currently scheduled meetings relevant to this application are as follows:

Meeting	Date
Initial Labeling Review (Email meeting)	February 12, 2016
Mid-Cycle Meeting	February 26, 2016
Internal Late-Cycle Meeting	April 26, 2016
External Late-Cycle Meeting	May 25, 2016

Discussion:

Each discussion point has been extracted from the reviewer's filing checklist. Only the filing decision and noteworthy findings are mentioned in this summary; for a detailed summary, please refer to each review discipline checklist.

APLB – Promotional Labeling

- The application is complete and may be filed
- The applicant has not submitted a request for Proprietary Name Review

Bioresearch Monitoring

- The application is complete and may be filed

Clinical

- The application is complete and may be filed

Clinical Pharmacology

- The application is complete and may be filed
- No deficiencies are noted, but PK data need to be reanalyzed by the sponsor.

CMC

- The application is complete and may be filed

DBSQC

- The application is complete and may be filed
- IR for sterility and endotoxin has been sent out and received. Review is in process.
- Possible misuse of (b) (4) Reference Standard
 - Presently under discussion with Review Committee Chair.
- (b) (4) is only partially validated and IR will follow.

DMPQ

- The application is complete and may be filed

Epidemiology

- The application is complete and may be filed

Pharmacology/Toxicology

- The application is complete and may be filed
- The label does not contain a nonclinical section (section 13). The applicant should summarize the available nonclinical data as specified by PLR (codified in 21 CFR 201.56 and 57).
 - The applicant may be notified in the filing letter.

Regulatory Management

- The application is complete and may be filed
- The applicant has not submitted a request for Proprietary Name Review

Statistics

- The application is complete and may be filed

Post Meeting Note:

- The applicant has communicated with the RPM that it intends to submit a request for proprietary name review; the date of submission has not been specified.

Action Items:

- Issue Filing notification letter – Due November 13, 2015
- Proprietary name review pending submission

END