



Filing Meeting Summary

Application: BL 125590/0
Product: Immune Globulin Intravenous (Human)
Proposed Indication: Treatment of primary humoral immunodeficiency
Applicant: ADMA Biologics, Inc.
Meeting Date & Time: Monday, September 14, 2015, 2:00 PM to 3:00 PM
Meeting Chair: Pei Zhang
Meeting Recorder: Yu Do

Agenda and Discussion

1. Introduction – Meeting Participants

Review Committee:

- a) Chair (CMC/Product) – Pei Zhang
- b) CMC - Lu Deng
- c) CMC – Lilin Zhong
- d) CMC - Maria Luisa Virata
- e) CMC - Yonggang Wang
- f) Pharmacology/Toxicology- Evi Struble
- g) Clinical Safety and Efficacy - Charles Maplethorpe
- h) Pharmacovigilance/Epidemiology - Wambui Chege
- i) Bioresearch Monitoring (BIMO) - Haecin Chun
- j) Bioresearch Monitoring (BIMO) - Anthony Hawkins
- k) Facilities and Inspection (DMPQ) - Michael Vardon
- l) Product Quality (DBSQC) - Marie Anderson

Iftekhar Mahmood, Alpita Popat, and Boris Zaslavsky, did not attend this meeting, but they reported on the filing status of this application prior to the meeting.

(Team Leads/Supervisors)

Mike Kennedy
Karen Campbell

(Division Director)

Mahmood Farshid

2. Introduction – Application/Product

ADMA Biologics, Inc. (ADMA) submitted this Biologics License Application (BLA) for RI-002, plasma-derived immunoglobulin product supplied as 10% solution for intravenous infusion and indicated to treat primary humoral immunodeficiency. ADMA is utilizing Biotest Pharmaceuticals, Inc. (Biotest) as the contract manufacturer for drug substance and (b) (4) as the contract manufacturer for drug product.

Receipt Date: July 31, 2015

Filing Checklist:

Supervisory concurrence - September 18, 2015

EDR upload – September 24, 2015

Filing Date: September 29, 2015

Day-74 Deficiencies Identified Letter: October 13, 2015

Proprietary Name Review: November 9, 2015

PeRC Date: May 18, 2016

Mid-Cycle Meeting: January 07, 2016

Mid-Cycle Communication: January 19, 2016

Late-Cycle Internal Meeting: March 14, 2016

T-Minus Date: July 16, 2016

PDUFA Action Due Date: July 30, 2016

3. A description of any required material that may have been omitted from the application:

Pharmacology/Toxicology – Nonclinical information was omitted in the original submission, but ADMA submitted this information on Thursday, September 10, 2015 as Amendment 0007 in response to CBER's request made during a teleconference. [Evi Struble]

Product Quality – Lot release protocol is missing in the submission. This information, however, will be requested, and its omission does not constitute a substantive filing deficiency. [Marie Anderson]

No other required materials have been omitted from the application.
[Review Committee]

4. Any substantive deficiencies or issues that potentially have significant impact on the ability to complete the review or approve the application

The application has no substantive deficiencies or issues that have significant impact on the ability to complete its review.

CMC – Issues surrounding postmarketing studies will be addressed later in the review cycle. [Pei Zhang and Michael Kennedy]

5. Comments on the status of the proprietary name review

The requested proprietary name (b) (4) was found unacceptable by a clinical reviewer. The Proprietary Name Non-Acceptance (PNN) letter will soon be issued.
[Charles Maplethorpe and Yu Do]

6. A proposal on whether the product would be subject to lot release, surveillance, or exempt from lot release

This product is subject to surveillance or lot release. [Michael Kennedy]

7. A discussion on the need for an RTF or deficiencies-identified letter

There is no need for an RTF or deficiencies-identified letter at this time.
[Review Committee]

8. A decision on filing, deficiencies identified, or RTF:

There is a consensus among the discipline reviewers that this application is complete and can be filed. [Review Committee]

9. A decision regarding standard or priority review status :

Standard status is granted for review of this application. [Pei Zhang]

10. A decision regarding the need for an Advisory Committee

There is no need at this time to present this application to an Advisory Committee.
[Pei Zhang]

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Drafted: Yu Do/September 14, 2015

Revised: Pei Zhang/September 21, 2015

Reviewed: Charles Maplethorpe/September 16, 2015

Reviewed: Wambui Chege/September 16, 2015

Reviewed: Anthony Hawkins/September 15, 2015