

Mid-Cycle Communication Telecon

Application type and number: BL 125587/0
Product name: Immune Globulin (Human) 10%
Proposed Indication: Primary humoral immunodeficiency (PI); Chronic immune thrombocytopenia (ITP) in adults
Applicant: Octapharma Pharmazeutika Produktionsges.m.b.H.
Meeting date & time: October 20, 2015; 1130 – 1230 ET
Committee Chair: Michael Kennedy, PhD, OBRR/DHRR
RPM: Christopher Hooban, MS, MPH, OBRR/RPMS

FDA Attendees:

Nannette Cagungan, MS, PD, RAC, OBRR/RPMS
Karen Campbell, OCBQ/DBSQC
Christopher Hooban, MS, MPH, OBRR/RPMS
Michael Kennedy, PhD, OBRR/DHRR
Christian Lynch, PhD, OCBQ/DMPQ
Randa Melhem, PhD, OCBQ/DMPQ
Yonggang Wang, PhD, OBRR/DHHR
Pei Zhang, MD, OBRR/DHHR

Eastern Research Group attendee:

Christopher Sese, Independent Assessor

Octapharma Pharmazeutika Produktionsges.m.b.H. Attendees:

Octapharma, France

Frederic Bal – Head of Quality Unit
Fanny Chauvel – General Manager
Didier Elmlinger – Head of Corporate Quality Control
Muriel Le Henaff – Head of Quality Assurance
Eric Penn – Plant Manager

Octapharma, Austria

Werner Giefing – Head of Quality Assurance & Quality in Operations
Günter Iberer – Head of Production
Harald Mayer – Head of Operation Support
Barbara Pyringer – Clinical Project Director
Barbara Rangetiner – Head of Regulatory Affairs
Jürgen Römisch – Senior Vice President R&D Plasma
Andreas Summerer – Head of Pharmaceutical Production
Birgit Taumberger – Clinical Project Manager
Balazs Toth – Drug Safety Officer/CDSU Physician
Josef Weinberger – Corporate Quality and Compliance Officer
Silvio Wuschko – Director Pharmacology and Toxicology

Marlene Krammer – Regulatory Affairs Manager

Octapharma, USA

Stanley Ammons – Senior Director, Compliance & Government Policy

Tor-Einar Svae – Senior Vice President Scientific & Medical Affairs

Octapharma, Springe, Germany

Gerold Rempeters – General Manager, Chief Production Officer

Octapharma, Frankfurt, Germany

Kai-Uwe Radomski – Deputy Head of Virus and Prion Validation

Torben Schmidt – Head of Virus and Prion Validation

Octapharma, Switzerland

Dirk Moritz – VP Head of IBU Immunotherapy

Ursula Konheiser – Senior International Product Manager

Susanne Schön - Junior International Product Manager

Agenda:

1. Significant issues/major deficiencies identified by the review committee to date:

Form 483:

- a. Responses will be reviewed when received.

CMC

- b. Measles specification
- c. Identity testing
- d. Use of (b) (4) during Nanofiltration

Pharmacology/Toxicology:

- e. No significant issues or major deficiencies.

Clinical:

- f. No significant issues or major deficiencies.

BIMO:

- g. No significant issues or major deficiencies.

Epidemiology/Pharmacovigilance Plan:

- h. No significant issues or major deficiencies.

Biostatistics:

- i. No significant issues or major deficiencies.

Advertising and Promotional Labeling:

j. No significant issues or major deficiencies.

2. The review of the clinical data to date did not raise major safety concerns.
3. At this time, routine pharmacovigilance is adequate to monitor the important identified and potential risks and missing information as described in the proposed pharmacovigilance plan.
4. Any information requests sent and not received

Date Sent	Expected Receipt Date
5-Oct-15	30-Oct-15
30-Sep- 15	21-Oct-15

5. Any new information requests to be communicated

N/A

6. Proposed date(s) for the late-cycle meeting

January 7, 2016 (1100 – 1300 ET)

7. Updates regarding plans for the AC meeting

N/A

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates.

Labeling Target Date	3/15/16
PMC Target Date	3/15/16
First Action Due	4/14/16

Discussion Summary:

The meeting began with the introduction of all participants (FDA followed by Octapharma). After introductions, the chair (Dr. Michael Kennedy) reviewed the issues identified in the agenda provided to the applicant prior to the meeting. With regards to item 1a of the agenda (483 responses), Dr. Kennedy stated that there would be no additional comments provided to the applicant. The information provided to the applicant upon delivery of Form 483 was deemed sufficient. The FDA would provide feedback upon receipt of the written responses. The applicant had no objections.

CMC items pertaining to measles specification, identity testing, and use of (b) (4) during nanofiltration were discussed previously with the applicant during the facility inspection. Dr. Kennedy provided a brief summary of these issues. He requested clarification on the use of an (b) (4) filter ((b) (4) filter). He indicated that use of the (b) (4) filter would be a rare and unusual event which would need to be notified to the FDA. Upon completion of the review of issues, Dr. Kennedy provided the applicant an opportunity to request additional information or express any concerns. The applicant had some questions regarding these three CMC items. Dr. Kennedy informed the applicant that the issues may be addressed after review of information request responses from the applicant.

Upon completion of the meeting, Octapharma indicated that they were satisfied with the information and responses provided during the meeting. The RPM, Christopher Hooban, reminded the applicant of the upcoming milestones listed in the agenda. The applicant verified that the proposed date for the late-cycle meeting was acceptable.