

**Clinical Pharmacology Filing Checklist  
Application Information**

**BLA/NDA Number:** 125590  
**Proprietary Name:** RI-002  
**Established/Proper Name:** Human immunoglobulin  
**Proposed indication(s):** Intended for the treatment of primary immunodeficiency diseases (PIDD)  
**Applicant:** ADMA Biologics, Inc.  
**Submission Date:** July 31, 2015  
**Date of Filing Meeting:** September 14, 2015  
**Filing Date:** September 29, 2015  
**Action Due Date:** July 29, 2016  
**Reviewer:** Iftekhar Mahmood, Ph.D.  
**Reviewer's Office/Division:** OBRR/DHR

**IS THE APPLICATION FILEABLE?  Yes /  No**

1. This application can be filed.
2. There is no deficiency but PK data need to be reanalyzed by the sponsor.
3. From clinical pharmacology perspective there is no innovative work in this submission.