

## RECORD OF TELEPHONE CONVERSATION

**Submission ID:** BL 125590/0  
**Review Office:** OBRR  
**Product:** Immune Globulin Intravenous (Human), 10% Liquid  
**Indication:** Treatment of primary humoral immunodeficiency  
**Sponsor:** ADMA Biologics, Inc. (ADMA)

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**Date/Time:** September 09, 2015, 9:00 AM to 9:15 AM  
**Initiated by FDA?** Yes.  
**Telephone Number:** (866) 398-2885, passcode (b) (4)  
**Author:** Yu Do  
**Purpose:** To discuss issues associated with omission of nonclinical study reports in the submission and to request any related information for review.

### **FDA Participants:**

Yu Do, MS, RPMS/IO/OBRR  
Dorothy Scott, MD, LPD/DHRR/OBRR  
Evi Struble, PhD, LPD/DHRR/OBRR  
Pei Zhang, MD, LPD/DHRR/OBRR

### **ADMA/MCG Participants:**

Diane P. Myers, Regulatory Consultant, Malvern Consulting Group (MCG)  
Gerri Henwood, Development Consultant, MCG  
Randall Mack, Development Consultant, MCG  
Alex Freyer, PharmD, Development Consultant, MCG  
(b) (4)  
James Mond, MD, Chief Scientific Officer, Chief Medical Officer, ADMA  
Lucy DeMario, PhD, Senior Director, Quality, ADMA  
(b) (4)

**Amendments:** 0005

### **Summary of Discussion**

Despite ADMA's justification (Amendment 0005), FDA made it clear to them that nonclinical study reports have been omitted in entirety and need to be submitted, even partially, in support of this original BLA submission. FDA requested that ADMA provide a summary of nonclinical information and toxicological assessment of their IGIV preparation, along with literature references, by the end of the week to evaluate for potential filing deficiencies before the filing meeting.

Additionally, FDA asked for more safety data and information related to active ingredient and excipients (e.g., Polysorbate 80).

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ADMA agreed and asked if it would be acceptable to submit the requested information as e-mail attachment(s) first and then formally later via Electronic Submission Gateway (ESG) for expeditious response.

FDA agreed with ADMA's proposal for submitting their response as long as there is no discrepancy between the two versions.

*Signature:* \_\_\_\_\_

Drafted: Yu Do/September 09, 2015

Reviewed: Evi Struble/September 11, 2015