



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Manufacturing and Product Quality

To: Administrative File: STN 125590/0.42, IMMUNE GLOBULIN INTRAVENOUS (HUMAN), 10% LIQUID

From: Anthony F. Lorenzo, Lead CSO, CBER/OCBQ/DMPQ/MRB2

Through: CDR Qiao Bobo, Ph.D., Branch Chief, CBER/OCBQ/DMPQ/MRB2

CC: LCDR Silvia Wanis, Pharm D., CBER/OCBQ/DMPQ/MRB2
Pei Zhang, Chair, CBER/OTAT/DPPT
Yu Do, RPM, CBER/OTAT/DRPM

Subject: **Review Memo:** ADMA Biologics Inc. (ADMA) Complete Response Letter response to item #4

Action Due Date: April 2, 2019

Recommendation: Approval

SUMMARY

ADMA's response to the Complete Response Letter (CRL) comment #4 from July 29, 2016 included an alternate sterile filling site at (b) (4). The qualification of (b) (4) as an alternate filling facility and equipment are reviewed in this document. PPQ was performed with BIVIGAM, an (b) (4) Immune Globulin Intravenous (IGIV) using (b) (4) manufacturing process, container closure system, and process equipment used to fill the submission's RI-002 product.

REVIEW

The (b) (4) RI-002 drug product batches referenced in the original BLA were filled on (b) (4) filler. The (b) (4) equipment has since been decommissioned and is being replaced with a new filling machine with a similar product handling design. The (b) (4) most recent batches of RI-002 were not filled at (b) (4) due to the timing and scheduling of their decommissioning/recommissioning of equipment. These (b) (4) conformance lots of RI-002 were filled at an alternate fill site, (b) (4) located at the following address:

(b) (4)



