Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

To:	BLA Efficacy Supplement 125105/2023
From:	Evi Struble, Ph.D., Research Pharmacology, PDB I, DPD, OPPT, OTAT
Through:	Dorothy E. Scott, M.D., Division Director, DPD, OPPT, OTAT
Applicant:	Baxalta US Inc.
Product:	Immune Globulin Infusion 10% (Human), GAMMAGARD LIQUID
Indication:	Chronic Inflammatory Demyelinating Polyneuropathy
Subject:	Preclinical Pharmacology Toxicology Review

Contents

Introduction

The application is an efficacy supplement to expand the indication of Gammagard Liquid to include the indication of therapy to improve neuromuscular disability and impairment in adult patients with Chronic Inflammatory Demyelinating Polyneuropathy. Gammagard Liquid has been approved for primary immunodeficiency disease and Multifocal Motor Neuropathy in adults since 2005.

Pharmacology and Toxicology

No new pharmacology and toxicology studies were submitted with this efficacy supplement. This is acceptable given the 1) nonclinical program completed to support the original BLA submission, and 2) clinical experience with the product since its original approval.

Recommendation

Approval is recommended from this discipline point of view.