



MEMORANDUM

Date: June 11, 2024

From: Mona Badawy
Regulatory Project Manager
RPM, Division of Review Management and Regulatory Review 2

Through: Edward Thompson
Branch Chief, Division of Review Management and Regulatory Review 2

To: BLA125810/0

Action Due Date: June 29, 2024

Applicant: Biotest AG

Product: Immune Globulin Intravenous (Human)

Subject: Review of Biotest AG’s Package (Carton) Labels, Container Labels,
National Drug Code (NDC), Associate Bar Codes, and Product Identifiers

Materials Reviewed (as Applicable):

Material	Receipt Date	Amendment #	NDC numbers	Strength
Package (Carton)	June 30, 2023	BLA 125810/0	83372-605-01	50 mL
			83372-605-11	100 mL
			83372-605-21	200 mL
Container	June 30, 2023	BLA 125810/0	83372-605-02	50 mL
			83372-605-12	100 mL
			83372-605-22	200 mL

The applicant submitted:

- Original Application
- Changes Being-Effectuated (CBE)- labeling supplement
- Prior Approval Supplement (PAS)
- Major Amendment
- Product Correspondence for License
- Annual Report

Background:

Biotest AG submitted BLA 125810/0 on June 30, 2023 for immune globulin intravenous, human - dira, 10% liquid indicated for the treatment of primary humoral immunodeficiency (PI) in patients 2 years of age or older.

Review and Communications:

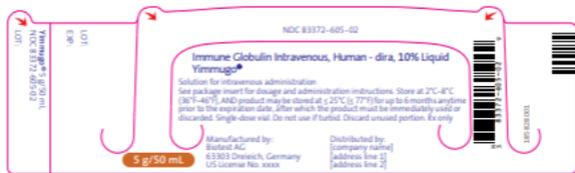
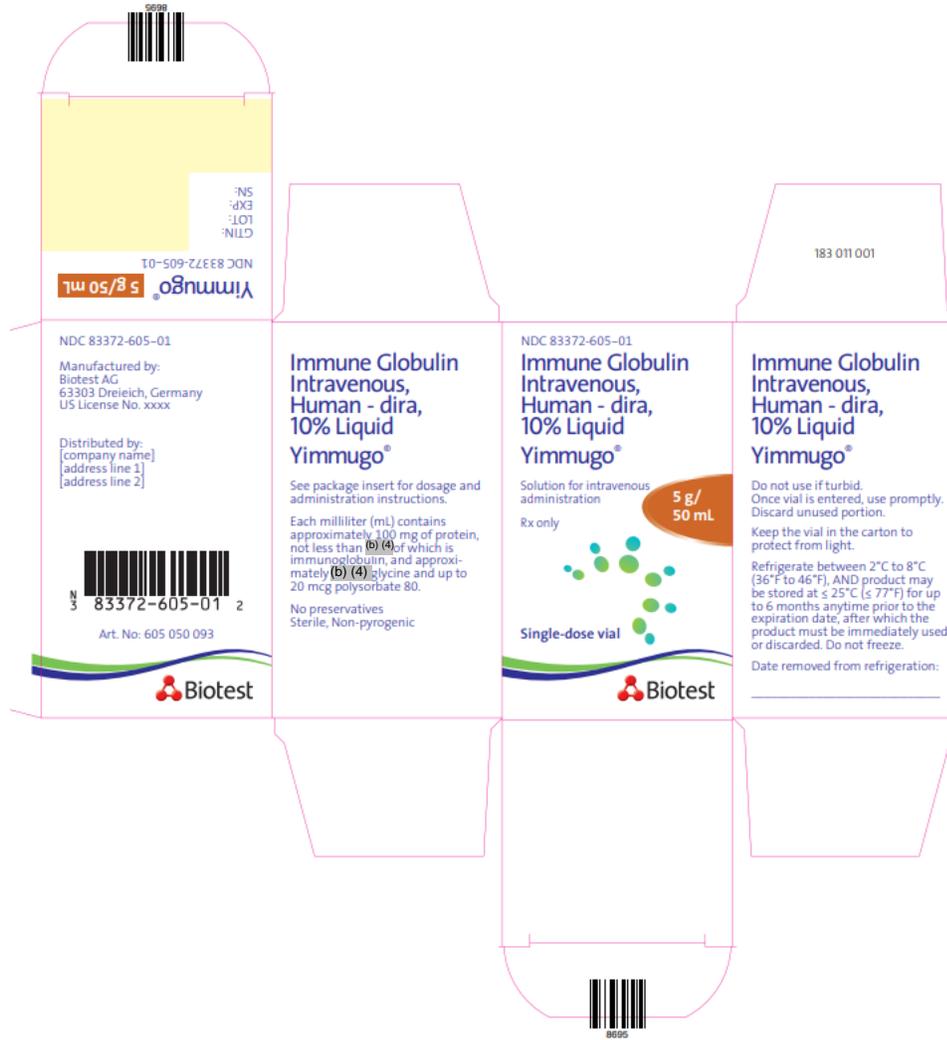
The review of this product's NDC did not reveal significant issues.

<u>Dosage/Package Level</u>	<u>NDC</u>
50 mL/ Carton	83372-605-01
100 mL/ Carton	83372-605-11
200 mL/ Carton	83372-605-21
50mL/ Container	83372-605-02
100 mL/ Container	83372-605-12
200 mL/ Container	83372-605-22

Recommendations:

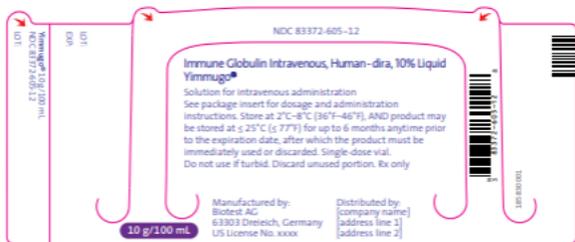
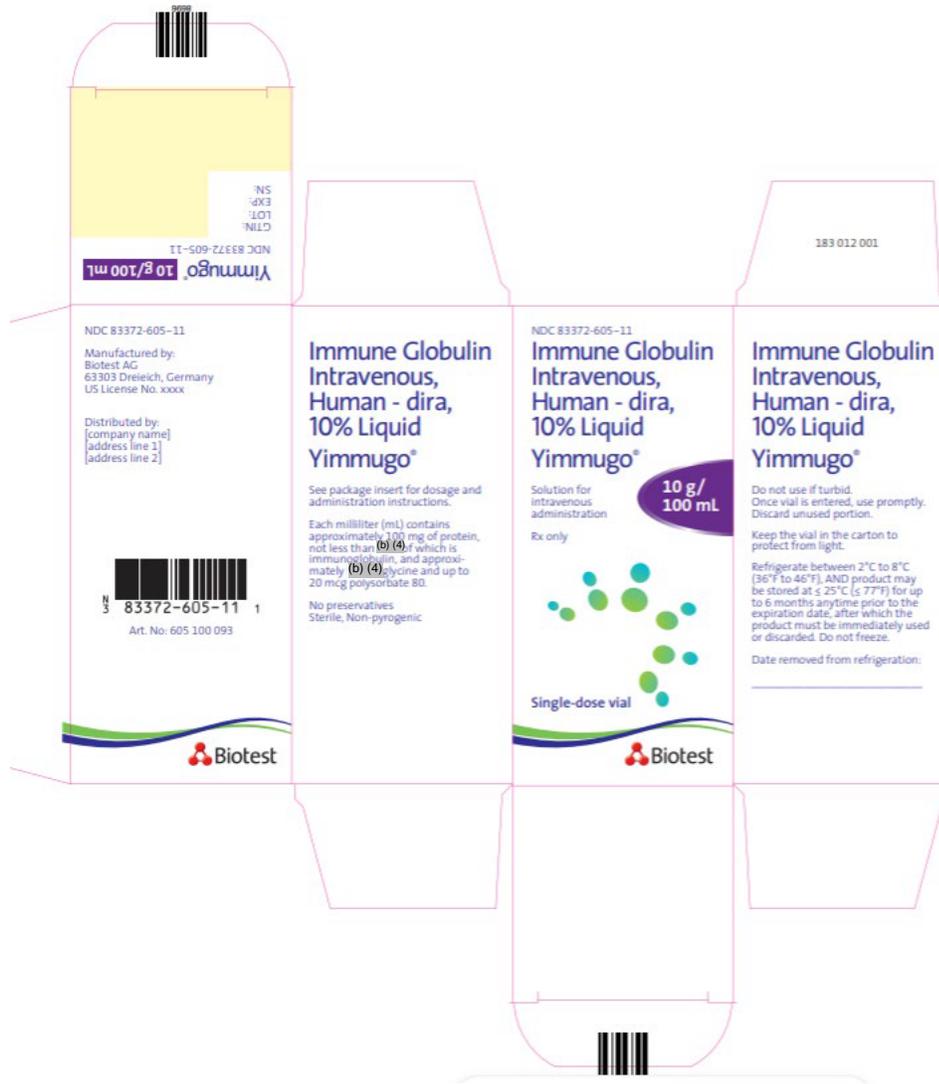
This original submission can be approved regarding the NDC assignment.

An illustration of Applicant's INITIAL Carton and Container label (50 mL)



all colors | illustration 100.0% | position of the label: end of the lines ahead ⇨

An illustration of Applicant's INITIAL Carton and Container label (100 mL)



all colors | illustration 100.0% | position of the label: end of the lines ahead ⇔

An illustration of Applicant's INITIAL Carton and Container label (200 mL)



all colors | illustration 100.0% | position of the label: end of the lines ahead ⇨

Mona Badawy
RPM

June 11, 2024
Date

Edward Thompson
Branch Chief

June 11, 2024
Date