



C 910.07: Regulatory Labeling Review

For procedures refer to [JA 900.08 Regulatory Labeling Review](#)

<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH</b>
<b>STN:</b> BLA 125810/0
<b>Manufacturer:</b> Biotest AG
<b>Diluent Manufacturer (as applicable):</b>
<b>Product:</b> Immune Globulin Intravenous (Human)
<b>RPM:</b> Mona Badawy
<b>BC:</b> Edward Thompson
<b>Clinical Reviewer:</b> Afsah Amin
<b>CMC Reviewer: Chair:</b> Jennifer Reed
<b>APLB Reviewer:</b> Sonny Saini

Table 1: Package Linear Barcode Review

Package Linear Barcode	Yes/No	Comment
Applicant submitted an exemption request from the linear barcode requirements	No	
Applicant is granted exemption request from linear barcode requirement	No	
Product is exempted from linear barcode requirements (21 CFR 201.25)	No	
A linear barcode is present	Yes	Linear barcode present on each package (50,100,200 mL)
The linear barcode is surrounded by sufficient blank space so that the barcode can be scanned correctly (per 21 CFR 201.25(c)(1)(i))	Yes	Linear barcode surrounded by sufficient blank space each package (50,100,200 mL)

Table 2: Container Linear Barcode Review

Container Linear Barcode	Yes/No	Comment
Applicant submitted an exemption request from the linear barcode requirements	No	
Applicant is granted exemption request from linear barcode requirement	No	
Product is exempted from linear barcode requirements (21 CFR 201.25)	No	



<b>Container Linear Barcode</b>	<b>Yes/No</b>	<b>Comment</b>
A linear barcode is present	Yes	
The linear barcode is surrounded by sufficient blank space so that the barcode can be scanned correctly (per 21 CFR 201.25(c)(1)(i))	Yes	

Table 3: 2D Barcode Review

<b>Package Product Identifier: 2D Barcode (non-linear) review under the DSCSA</b>	<b>Yes/No</b>	<b>Comment</b>
Applicant is requesting either a waiver, exception, or exemption (WEE) from DSCSA requirements	No	
Applicant is granted waiver, exception, or exemption from DSCSA requirements	No	
Non-linear (2D barcode) is present	Yes	Linear barcode present on each package (50,100,200 mL)
The human-readable portion of the product identifier that is required under the DSCSA is present:  NDC: 83372-605-01 SERIAL: LOT: [insert product's lot number] EXP: [insert product's expiration date]	Yes	
The DSCSA elements do not include the NDC, but the NDC is located near the required elements	Yes	



Table 4: Package NDC Review

<b>Package NDC</b>	<b>Yes/No</b>	<b>Comment</b>
Labeler code (First segment of NDC) is valid	Yes	50 mL- 83372-605-01 100 mL-83372-605-11 200 mL-83372-605-21
Product code (second segment of NDC) is appropriate for the package and container and the configuration is consistent with the other NDCs	Yes	50 mL- 83372-605-01 100 mL-83372-605-11 200 mL-83372-605-21
Package code (third segment of NDC) is appropriate for the package and container and the configuration is consistent with the other NDCs	Yes	50 mL- 83372-605-01 100 mL-83372-605-11 200 mL-83372-605-21
The NDC is listed in the principal display panel and/or near the 2D barcode and linear barcode, as applicable	Yes	
NDCs are consistent with the NDCs listed in section 16 HOW SUPPLIED/STORAGE AND HANDLING OF THE PI (in the SPL and Word versions)	Yes	

Table 5: Container NDC Review

<b>Container NDC</b>	<b>Yes/No</b>	<b>Comment</b>
Labeler code (First segment of NDC) is valid	Yes	50mL- 83372-605-02 100 mL- 83372-605-12 200 mL- 83372-605-22
Product code (second segment of NDC) is appropriate for the package and container and the configuration is consistent with the other NDCs	Yes	50mL- 83372-605-02 100 mL- 83372-605-12 200 mL- 83372-605-22
Package code (third segment of NDC) is appropriate for the package and container and the configuration is consistent with the other NDCs	Yes	50mL- 83372-605-02 100 mL- 83372-605-12 200 mL- 83372-605-22
The NDC is listed in the principal display panel and/or near the 2D	Yes	NDC is listed near the barcode



Container NDC	Yes/No	Comment
barcode and linear barcode, as applicable		
NDCs are consistent with the NDCs listed in section 16 HOW SUPPLIED/STORAGE AND HANDLING OF THE PI (in the SPL and Word versions)	Yes	

**Note: Review package and container labeling for completeness and not for layout and accuracy. If an element is missing/not known notify/consult Clinical/CMC/APLB reviewer(s).**

Table 6: Package and Container Review

Package AND container bearing a full label	Yes/No	Comment
Proper Name of the product (610.62 position, prominence, and legible type- APLB responsibility)	Yes	
Manufacturer’s Name, address, and license number (or applicant’s license number)	Yes	<b>Manufactured by:</b> Biotest AG 63303 Dreieich, Germany U.S. license no: 2332
Lot Number or other lot identification	Yes	
Expiration Date	Yes	
"Rx only" for prescription products	Yes	For each 50, 100, and 200mL Package and container

Table 7: Container Review

Yes

Container Label	Yes/No	Comment
The recommended individual dose, for multiple dose containers (for single-patient use or multiple-patient use)”	Yes	Single dose vial
If a Medication Guide is required under <a href="#">part 208 of this chapter</a> , the statement required under <a href="#">§ 208.24(d) of this chapter</a> instructing the authorized dispenser to provide a	No	



<b>Container Label</b>	<b>Yes/No</b>	<b>Comment</b>
Medication Guide to each patient to whom the drug is dispensed and stating how the Medication Guide is provided, except where the container label is too small, the required statement may be placed on the package label.		
If the container is not enclosed in a package, all the items required for a package label shall appear on the container label	No	
If the container is capable of bearing only a partial label, the container shall show as a minimum elements <b>a-f</b> as listed above. Containers bearing partial labels shall be placed in a package which bears all the items required for a package label.	No	
If the container is incapable of bearing any label, the items required for a container label may be omitted, provided the container is placed in a package which bears all the items required for a package label	No	
When the label has been affixed to the container a sufficient area of the container shall remain uncovered for its full length or circumference to permit inspection of the contents.	No	

Table 8: Package Review

<b>Package Label</b>	<b>Yes/No</b>	<b>Comment</b>
Preservative used and its concentration OR if no preservative is used and the absence of a preservative is a safety factor, the words "no preservative"	Yes	No preservatives Sterile, Non-pyrogenic
Number of containers, if more than one	Yes	One container per package
Amount of product (e.g., number of doses, volume, weight, units of potency)	Yes	5gm/50mL 10gm/100mL 20mg/200mL
Storage Temperature		Refrigerate between 2°C to 8°C



Package Label	Yes/No	Comment
		(36°F to 46°F), AND product may be stored at ≤ 25°C (≤ 77°F) for up to 6 months
The words “Shake Well”, “Do not Freeze” or the equivalent, as well as other instructions, when indicated by the character of the product	Yes	Protect from light
The recommended individual Dose if the enclosed container(s) is a multiple-dose container	Yes	Single dose vial
Route of administration recommended, or reference to such directions in an enclosed circular	Yes	IV
Known sensitizing substances, or reference to an enclosed circular containing appropriate information	No	
Type and calculated amount of antibiotics added during manufacturing	No	
The inactive ingredients when a safety factor, OR reference to an enclosed circular containing appropriate information;	No	
Adjuvant, if present	No	
The source of the product when a factor in safe administration	No	
Identity of each microorganism used in manufacture, and where applicable, the production medium and the method of inactivation, or reference to an enclosed circular containing appropriate information	No	
Minimum potency of product expressed in terms of official standard of potency or, if potency is a factor and no U.S. standard of potency has been prescribed, the words “No U.S. standard of potency.”	No	
<b>Divided manufacturing responsibility to be shown (21 CFR 610.63)</b> If two or more licensed manufacturers participate in the manufacture of a biological product, the name, address, and license	No	<b>Manufactured by:</b> Biotest AG 63303 Dreieich, Germany



Package Label	Yes/No	Comment
number of each must appear on the package label, and on the label of the container if capable of bearing a full label.		
<b>Name and address of distributor (21 CFR 610.64)</b> The name and address of the distributor of a product may appear on the label provided that the name, address, and license number of the manufacturer also appears on the label and the name of the distributor is qualified by one of the following phrases: “Manufactured for _____”, “Distributed by _____”, “Manufactured by _____ for _____”, “Manufactured for _____ by _____”, “Distributor: _____”, or “Marketed by _____”. The qualifying phrases may be abbreviated.	No	

Table 9: Diluent Review

Diluent	Yes/No	Comment
Volume	N/A	
Lot Number (depending on the diluent it would not need a lot number)	N/A	
Expiration Date	N/A	
Manufacturer’s Name and address	N/A	
If U.S.P. monograph <sup>1</sup> name is used, includes monograph labeling requirements	N/A	
Linear Barcode	N/A	
NDC in human readable format	N/A	