DEPARTMENT OF HEALTH & HUMAN SERVICES
FDA/CBER/OVRR/DVRPA

Memorandum

Date: August 20, 2021

From: Daphne D. Stewart, CSO
Regulatory Management Support Branch,
DVRPA/OVRR

Through: Tim D. Nelle, Ph.D., CAPT U.S. Public Health Service,
Branch Chief, RMSB

To: BLA STN 125742/0 File

Subject Review of BioNTech Manufacturing GmbH – BLS 125742/0
COVID-19 mRNA Vaccine (nucleoside modified) – COMIRNATY®
Carton and Container Labeling

Background

This Biologic License Application (BLA) is for COVID-19 mRNA Vaccine (nucleoside modified) – COMIRNATY® which is indicated for active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older. This submission on contains the following labels that are the subject of this review:

- Single-Dose 2 mL (25 Doses) Diluent Sodium Chloride Injection, USP 0.9% Vial Carton Label – Fresenius Kabi
- Single-Dose 2 mL Diluent Sodium Chloride Injection, USP 0.9% Vial Container Label – Fresenius Kabi
- Multiple-Dose 10 mL (25 Doses) Diluent 0.9% Sodium Chloride Injection, USP Vial Carton Label – (b) (4) Hospira
- Single-Dose 10 mL Diluent Sodium Chloride Injection, USP 0.9% Vial Container Label – (b) (4) Hospira
- Fresenius Kabi Diluent Stamp
- Hospira Diluent Sticker Label
- Multiple-Dose (25 Doses) Vial Carton Label – Kalamazoo, MI and Puurs, Belgium
- Multiple-Dose (195 Doses) Vial Carton Label Kalamazoo, MI and Puurs, Belgium
- Single-Dose 0.3 mL Vial Container Label – Kalamazoo, MI and Puurs, Belgium

These labels were reviewed for compliance with the regulations 21 CFR 201.25 & 21 CFR 207.35, Subpart G – Labeling Standards 21 CFR 610.60 (a)(1) through (7) and 21 CFR 610.60 (7) (b) through (e), 21 CFR 610.62 (a) through (c), 21 CFR 610.63, 21 CFR 610.64, 21 CFR 610.67, the Drug Supply Chain Security Act (DSCSA) and CBER Job Aid 900.08: National Drug Code, Bar Code

and Product Identifier. To ensure completeness, the CBER checklists were used during this review; however, only the checklists for the final draft labels are attached to this review (see Appendixes). In each checklist, an "x" next to each item denotes that the label was found to be compliant with the corresponding regulation.

Multiple-Dose 2 mL (25 Doses) Diluent 0.9% Sodium Chloride Injection, USP Vial Carton Label – Fresenius Kabi (NDC 63323-186-02):

> The original carton label that was provided consisted of a container label with the NDC stamped onto the carton. The agency requested that the applicant have separate labels for the carton and the container on August 9, 2021. In response, the applicant submitted a revised diluent carton and a separate diluent container label on August 17, 2021, and again on August 19, 2021. After review, it was determined that this carton label is approvable. Please see Appendix 1 for full review.

Single-Dose 2 mL Diluent Sodium Chloride Injection, USP 0.9% Vial Container Label – Fresenius Kabi (NDC 63323-186-04):

> The applicant submitted this container label on August 17, 2021, and again on August 19, 2021. This container label is approvable. Please see Appendix 2 for full review.

Multiple-Dose 10 mL (25 Doses) Diluent 0.9% Sodium Chloride Injection, USP Vial Carton Label – (b) (4) *Hospira* (NDC 0409-4888-10)

> The original label did not include the diluent proper name, the product identifier, the lot number, or expiration date. It also was identical to the vial label. After being notified on August 9, 2021, the applicant submitted a revised label that addressed these deficiencies on August 13, 2021; August 17, 2021; and again on August 19, 2021. This label is acceptable for approval. Please see Appendix 3 for full review.

Single-Dose 10 mL Sterile Diluent Vial Container Label (NDC 0409-4888-02)
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> The applicant submitted a container label for their Diluent 0.9% Sodium Chloride Injection, USP Vial Carton Label – (b) (4) Hospira to CBER on August 17, 2021, and again on August 19, 2021. This label is acceptable for approval. Please see Appendix 4 for full review.

Fresenius Kabi Diluent Stamp (No NDC):

> The original label did not include the diluent proper name, the product identifier, the lot number, or expiration date. After being notified of these deficiencies on August 9, 2021, the applicant submitted a revised

Fresenius Kabi diluent stamp to CBER on August 13, 2021; and August 17, 2021. The applicant also attempted to submit a picture on August 19 but noted that they could not take a new picture of the stamp because the entire packaging line would have to be shut down. CBER responded that a picture wasn't required – only the information/text that would be included on the stamp is necessary is to submit at this time. The applicant acknowledged this and confirmed that: "The stamp will be updated so that it is alignment with the text included in the Diluent Sticker for Hospira (also provided in this submission)." This response was deemed sufficient. This label is acceptable for approval. Please see Appendix 5 for full review.

Hospira Diluent Sticker (Vial) Label (No NDC)

The original label did not include the diluent proper name, the product identifier, the lot number, or expiration date. After being notified of these deficiencies on August 9, 2021, the applicant submitted a revised Hospira diluent sticker to CBER on August 13, 2021; August 17, 2021; and again, on August 19, 2021. This label is acceptable for approval. Please see Appendix 6 for full review.

Multiple-Dose (25 Doses) Vial Carton Label (NDC 0069-1000-03) (both "Puurs" & "Kzoo")

The original labels did not include the Product Identifier, required by Drug Supply Chain Security Act (DSCSA) or the license number. The applicant was asked to address these deficiencies and revise the proper name to "COVID-19 Vaccine, mRNA" on August 9, 2021. Also, there was internal discussion about the placement of the QR Code and how it competes with, distracts from, and interrupts the carton label; however, it was decided no further action would be required this matter. The applicant submitted their revised labels for both locations to CBER on August 13, 2021; August 17, 2021; and again, on August 19, 2021. These labels are acceptable for approval. Please see Appendix 7 for full review.

Multiple-Dose (195 Doses) Vial Carton Label (NDC 0069-1000-02) (both "Puurs" & "Kzoo")

The original labels did not include the Product Identifier, required by Drug Supply Chain Security Act (DSCSA) or the license number. It was also not clear what information would be printed in both fields of the "Overprint Area". The applicant was asked to address these issues and revise the proper name to "COVID-19 Vaccine, mRNA" on August 9, 2021. Also, there was internal discussion about the placement of the QR Code and how it competes with, distracts from, and interrupts the carton label; however, it was decided no further action would be required for this

matter. The applicant submitted their revised labels (for both locations) on August 13, 2021; August 17, 2021, and again on August 19, 2021. These labels are acceptable for approval. Please see Appendix 8 for full review.

Single-Dose 0.3 Vial Container Label (NDC 0069-1000-01) (both "Puurs" & "Kzoo")

The original labels did not include license number. After being notified of this deficiency and the need to revise the proper name to "COVID-19 Vaccine, mRNA" on August 9, 2021, the applicant submitted revised labels for both locations on August 13, 2021, August 17, 2021, and again on August 19, 2021. These labels are acceptable for approval. Please see Appendix 9 for full review.

Recommendations

These labels are currently in compliance with 21 CFR 201.25, 21 CFR 207.35 and 21 CFR 610.60 through 21 CFR 610.67, Drug Supply Chain Security Act (DSCSA), the Guidance for Industry, "Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use", and CBER Job Aid 900.08: National Drug Code, Bar Code and Product Identifier. Therefore, these labels are recommended for approval.

Appendix 1: Review Checklist for Multiple-Dose 2 mL (25 Doses) Diluent 0.9% Sodium Chloride Injection, USP Vial Carton Label: (Package) Label – Fresenius Kabi (NDC 63323-186-02 submitted on August 17, 2021, and August 19, 2021.

21 CFR 610.61 (a) through (s)	Checked items "x" indicate compliance
a. The proper name of the product;	X
b. The name, address, and license number of manufacturer;	X
c. The lot number or other lot identification;	X
d. The expiration date;	X
e. The 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";	X
f. The number of containers, if more than one;	X
g. The amount of product in the container expressed as (1) the number of doses, (2) volume, (3) units of potency, (4) weight, (5) equivalent volume (for dried product to be reconstituted), or (6) such combination of the foregoing as needed for an accurate description of the contents, whichever is applicable;	X
h. The recommended storage temperature;	X
i. The words "Shake Well", "Do not Freeze" or the equivalent, as well as other instructions, when indicated by the character of the product;	X
j. The recommended individual dose, for multiple dose containers.	25 Doses
k. The route of administration recommended, or reference to such directions in an enclosed circular	X
l. Known sensitizing substances, or reference to an enclosed circular containing appropriate information;	X
m. The type and calculated amount of antibiotics added during manufacture;	X
n. The inactive ingredients when a safety factor, or reference to an enclosed circular containing appropriate information;	X
o. The adjuvant, if present;	N/A
p. The source of the product when a factor in safe administration;	X
q. The 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	X
r. 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."	X
s. The statement: "'Rx only'" for prescription biologicals.	X

JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	Checked items "x" indicate compliance
9. Barcode & Linear or One-Dimensional (1D) (Parallel Lines)	X
NDC	
a. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes (to check the sponsor's NDC)	X
b. Click "Open"	X
c. Click "ndc_hric_labeler_codes"	X
d. Click "Yes"	X
e. Locate the Firm Name and the NDC Labeler Code will be to the right	X
10. Detachable Portion If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode) The actual detach label needs to include: a. Proprietary Name b. NDC # c. Lot # & Expiry Date	N/A
If the detachable label cannot contain all the above information, then it should have: a. Proprietary Name b. NDC # c. Lot #	N/A
For 2D Barcodes on the carton label to meet the regulations for the Drug Supply Chain Security Act (DSCSA).	X
Product Identifier - 2D Barcode a. Locate the symbol and the datamatrix codes will consist of: NDC (01): EXPIRY (17): BATCH/LOT (10): SERIAL (21):	 X X X X

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use Guidance for Industry	**Checked items "x" indicate compliance**
a. Multiple-Dose b. Single-Dose c. Single-Patient-Use	x

11. *If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion.*	16 years of age and older
Comments: Diluent 0.9% Sodium Chloride Injection, USP Vial Carton Label – Fresenius Kabi This label is acceptable for approval.	

Appendix 2: Review Checklist for Single-Dose 2 mL Diluent Sodium Chloride Injection, USP 0.9% Vial Container Label – Fresenius Kabi (NDC 63323-186-04) submitted on August 17, 2021, and August 19, 2021.

21 CFR 610.60(a)(1) through (7)	Checked items "x" indicate compliance
a. *Full label.* The following items shall appear on the label affixed to each container of a product capable of bearing a full label:	X
* 1. The proper name of the product;	X
* 2. The name, address, and license number of manufacturer;	X
* 3. The lot number or other lot identification;	X
* 4. The expiration date;	X
* 5. The recommended individual dose, for multiple dose containers.	2 mL
* 6. The statement: "'Rx only'" for prescription biologicals.	X
7. If a Medication Guide is required under part 208 of this chapter, the statement required under §208.24(d) of this chapter instructing the authorized dispenser to provide a 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.	N/A

21 CFR 610.62 (7) (b) through (e)	Checked items "x" indicate compliance
b. *Package label information.* If the container is not enclosed in a package, all the items required for a package label shall appear on the container label.	N/A
c. *Partial label.* If the container is capable of bearing only a partial label, the container shall show as a minimum the name (expressed either as the proper or common name), the lot number or other lot identification and the name of the manufacturer; in addition, for multiple dose containers, the recommended individual dose. Containers bearing partial labels shall be placed in a package which bears all the items required for a package label.	X
d. *No container label.* 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.	N/A
e. *Visual inspection.* 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.	X

JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	
*8. Barcode Linear or One-Dimensional (1D) (Parallel Lines) NDC a. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes (to check the sponsor's NDC) b. Click "Open" c. Click "ndc_nhric_labeler_codes" d. Click "Yes" e. Locate the Firm Name and the NDC Labeler Code will be to the right	N/A N/A
*9. Product Identifier - 2D Barcode a. Locate the symbol and the datamatrix code information will consist of: NDC (01): EXPIRY (17): BATCH/LOT (10): SERIAL (21):	N/A
10. Detachable Portion If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode) The actual detach label needs to include: a. Proprietary Name b. NDC # c. Lot # & Expiry Date If the detachable label cannot contain all the above information, then it should have: a. Proprietary Name b. NDC # c. Lot #	N/A N/A

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use Guidance for Industry	**Checked items "x" indicate compliance**
a. Multiple-Dose b. Single-Dose c. Single-Patient-Use	x

11. *If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion.*	16 years of age and older
Comments: *2 mL Diluent Sodium Chloride Injection, USP 0.9% Vial Container Label – Fresenius Kabi*. This label is acceptable for approval.	

**** Minimum requirement for partial labels***

Appendix 3: Review Checklist for Multiple-Dose 10 mL (25 Doses) Diluent 0.9% Sodium Chloride Injection, USP Vial Carton Label: (Package) Label – (b) (4) Hospira (NDC 0409-4888-10) submitted on August 13, 2021; August 17, 2021; and August 19, 2021.

21 CFR 610.61 (a) through (s)	Checked items "x" indicate compliance
a. The proper name of the product;	X
b. The name, address, and license number of manufacturer;	X
c. The lot number or other lot identification;	X
d. The expiration date;	X
e. The 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";	X
f. The number of containers, if more than one;	X
g. The amount of product in the container expressed as (1) the number of doses, (2) volume, (3) units of potency, (4) weight, (5) equivalent volume (for dried product to be reconstituted), or (6) such combination of the foregoing as needed for an accurate description of the contents, whichever is applicable;	X
h. The recommended storage temperature;	X
i. The words "Shake Well", "Do not Freeze" or the equivalent, as well as other instructions, when indicated by the character of the product;	X
j. The recommended individual dose, for multiple dose containers.	25 Doses
k. The route of administration recommended, or reference to such directions in an enclosed circular	X
l. Known sensitizing substances, or reference to an enclosed circular containing appropriate information;	X
m. The type and calculated amount of antibiotics added during manufacture;	X
n. The inactive ingredients when a safety factor, or reference to an enclosed circular containing appropriate information;	X
o. The adjuvant, if present;	N/A
p. The source of the product when a factor in safe administration;	X
q. The 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	X
r. 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."	X
s. The statement: "'Rx only'" for prescription biologicals.	X

JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	Checked items "x" indicate compliance
9. Barcode & Linear or One-Dimensional (1D) (Parallel Lines) NDC b. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes (to check the sponsor's NDC) b. Click "Open" c. Click "ndc_hric_labeler_codes" d. Click "Yes" e. Locate the Firm Name and the NDC Labeler Code will be to the right	X X X X X X
10. Detachable Portion If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode) The actual detach label needs to include: a. Proprietary Name b. NDC # c. Lot # & Expiry Date	N/A
If the detachable label cannot contain all the above information, then it should have: a. Proprietary Name b. NDC # c. Lot # For 2D Barcodes on the carton label to meet the regulations for the Drug Supply Chain Security Act (DSCSA). Product Identifier - 2D Barcode b. Locate the symbol and the datamatrix codes will consist of: NDC (01): EXPIRY (17): BATCH/LOT (10): SERIAL (21):	N/A X X X X X

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use Guidance for Industry	**Checked items "x" indicate compliance**
d. Multiple-Dose e. Single-Dose f. Single-Patient-Use	x

11. *If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion.*	16 years of age and older
Comments: Diluent 0.9% Sodium Chloride Injection, USP Vial Carton Label – Fresenius Kabi This label is acceptable for approval.	

Appendix 4: Review Checklist for Single-Dose 2 mL Diluent Sodium Chloride Injection, USP 0.9% Vial Container Label – (b) (4) Hospira (NDC 63323-186-04) submitted on August 17, 2021, and August 19, 2021.

21 CFR 610.60(a)(1) through (7)	Checked items "x" indicate compliance
b. *Full label.* The following items shall appear on the label affixed to each container of a product capable of bearing a full label:	X
* 1. The proper name of the product;	X
* 2. The name, address, and license number of manufacturer;	X
* 3. The lot number or other lot identification;	X
* 4. The expiration date;	X
* 5. The recommended individual dose, for multiple dose containers.	2 mL
* 6. The statement: "'Rx only'" for prescription biologicals.	X
7. If a Medication Guide is required under part 208 of this chapter, the statement required under §208.24(d) of this chapter instructing the authorized dispenser to provide a 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.	N/A

21 CFR 610.62 (7) (b) through (e)	Checked items "x" indicate compliance
b. *Package label information.* If the container is not enclosed in a package, all the items required for a package label shall appear on the container label.	N/A
c. *Partial label.* If the container is capable of bearing only a partial label, the container shall show as a minimum the name (expressed either as the proper or common name), the lot number or other lot identification and the name of the manufacturer; in addition, for multiple dose containers, the recommended individual dose. Containers bearing partial labels shall be placed in a package which bears all the items required for a package label.	X
d. *No container label.* 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.	N/A
e. *Visual inspection.* 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.	X

JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	
*8. Barcode Linear or One-Dimensional (1D) (Parallel Lines) NDC b. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes (to check the sponsor's NDC) b. Click "Open" c. Click "ndc_nhric_labeler_codes" d. Click "Yes" e. Locate the Firm Name and the NDC Labeler Code will be to the right	N/A N/A
*9. Product Identifier - 2D Barcode a. Locate the symbol and the datamatrix code information will consist of: NDC (01): EXPIRY (17): BATCH/LOT (10): SERIAL (21):	N/A
10. Detachable Portion If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode) The actual detach label needs to include: a. Proprietary Name b. NDC # c. Lot # & Expiry Date If the detachable label cannot contain all the above information, then it should have: a. Proprietary Name b. NDC # c. Lot #	N/A N/A

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use Guidance for Industry	**Checked items "x" indicate compliance**
d. Multiple-Dose e. Single-Dose f. Single-Patient-Use	x

11. *If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion.*	16 years of age and older
Comments: *2 mL Diluent Sodium Chloride Injection, USP 0.9% Vial Container Label – Fresenius Kabi*. This label is acceptable for approval.	

**** Minimum requirement for partial labels***

Appendix 5: Review Checklist for Fresenius Kabi Diluent Stamp No NDC) submitted August 13, 2021; August 17, 2021; and August 19, 2021.

21 CFR 610.60(a)(1) through (7)	Checked items "x" indicate compliance
c. *Full label.* The following items shall appear on the label affixed to each container of a product capable of bearing a full label:	X
* 1. The proper name of the product;	X
* 2. The name, address, and license number of manufacturer;	X
* 3. The lot number or other lot identification;	X
* 4. The expiration date;	X
* 5. The recommended individual dose, for multiple dose containers.	Fresenius Kabi Diluent Stamp
* 6. The statement: "'Rx only'" for prescription biologicals.	X
7. If a Medication Guide is required under part 208 of this chapter, the statement required under §208.24(d) of this chapter instructing the authorized dispenser to provide a 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.	N/A

21 CFR 610.62 (7) (b) through (e)	Checked items "x" indicate compliance
b. *Package label information.* If the container is not enclosed in a package, all the items required for a package label shall appear on the container label.	N/A
c. *Partial label.* If the container is capable of bearing only a partial label, the container shall show as a minimum the name (expressed either as the proper or common name), the lot number or other lot identification and the name of the manufacturer; in addition, for multiple dose containers, the recommended individual dose. Containers bearing partial labels shall be placed in a package which bears all the items required for a package label.	X
d. *No container label.* 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.	N/A
e. *Visual inspection.* 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.	X

JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	
*8. Barcode Linear or One-Dimensional (1D) (Parallel Lines) NDC c. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes (to check the sponsor's NDC) b. Click "Open" c. Click "ndc_nhric_labeler_codes" d. Click "Yes" e. Locate the Firm Name and the NDC Labeler Code will be to the right	N/A N/A
*9. Product Identifier - 2D Barcode a. Locate the symbol and the datamatrix code information will consist of: NDC (01): EXPIRY (17): BATCH/LOT (10): SERIAL (21):	N/A
10. Detachable Portion If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode) The actual detach label needs to include: a. Proprietary Name b. NDC # c. Lot # & Expiry Date If the detachable label cannot contain all the above information, then it should have: a. Proprietary Name b. NDC # c. Lot #	N/A N/A

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use Guidance for Industry	**Checked items "x" indicate compliance**
g. Multiple-Dose h. Single-Dose i. Single-Patient-Use	N/A

11. *If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion.*	16 years of age and older
Comments: Fresenius Kabi Diluent Stamp. This label is acceptable for approval.	

**** Minimum requirement for partial labels***

Appendix 6: Review Checklist for Hospira Diluent Sticker Label (No NDC) submitted August 13, 2021; August 17, 2021; and August 19, 2021.

21 CFR 610.60(a)(1) through (7)	Checked items "x" indicate compliance
d. *Full label.* The following items shall appear on the label affixed to each container of a product capable of bearing a full label:	X
* 1. The proper name of the product;	X
* 2. The name, address, and license number of manufacturer;	X
* 3. The lot number or other lot identification;	X
* 4. The expiration date;	X
* 5. The recommended individual dose, for multiple dose containers.	Fresenius Kabi Diluent Stamp
* 6. The statement: "'Rx only'" for prescription biologicals.	X
7. If a Medication Guide is required under part 208 of this chapter, the statement required under §208.24(d) of this chapter instructing the authorized dispenser to provide a 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.	N/A

21 CFR 610.62 (7) (b) through (e)	Checked items "x" indicate compliance
b. *Package label information.* If the container is not enclosed in a package, all the items required for a package label shall appear on the container label.	N/A
c. *Partial label.* If the container is capable of bearing only a partial label, the container shall show as a minimum the name (expressed either as the proper or common name), the lot number or other lot identification and the name of the manufacturer; in addition, for multiple dose containers, the recommended individual dose. Containers bearing partial labels shall be placed in a package which bears all the items required for a package label.	X
d. *No container label.* 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.	N/A
e. *Visual inspection.* 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.	X

JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	
*8. Barcode Linear or One-Dimensional (1D) (Parallel Lines) NDC d. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes (to check the sponsor's NDC) b. Click "Open" c. Click "ndc_nhric_labeler_codes" d. Click "Yes" e. Locate the Firm Name and the NDC Labeler Code will be to the right	N/A N/A
*9. Product Identifier - 2D Barcode a. Locate the symbol and the datamatrix code information will consist of: NDC (01): EXPIRY (17): BATCH/LOT (10): SERIAL (21):	N/A
10. Detachable Portion If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode) The actual detach label needs to include: a. Proprietary Name b. NDC # c. Lot # & Expiry Date If the detachable label cannot contain all the above information, then it should have: a. Proprietary Name b. NDC # c. Lot #	N/A N/A

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use Guidance for Industry	**Checked items "x" indicate compliance**
j. Multiple-Dose k. Single-Dose l. Single-Patient-Use	N/A

11. *If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion.*	16 years of age and older
Comments: Hospira Diluent Sticker Label. This label is acceptable for approval.	

**** Minimum requirement for partial labels***

Appendix 7: Review Checklist for Multiple-Dose 10 mL (25 Doses) Sterile Diluent Carton Label (Package) Label: (NDC 0409-4888-02) submitted on August 13, 2021; August 17, 2021; and August 19, 2021.

21 CFR 610.61 (a) through (s)	Checked items "x" indicate compliance
a. The proper name of the product;	X
b. The name, address, and license number of manufacturer;	X
c. The lot number or other lot identification;	X
d. The expiration date;	X
e. The 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";	X
f. The number of containers, if more than one;	X
g. The amount of product in the container expressed as (1) the number of doses, (2) volume, (3) units of potency, (4) weight, (5) equivalent volume (for dried product to be reconstituted), or (6) such combination of the foregoing as needed for an accurate description of the contents, whichever is applicable;	X
h. The recommended storage temperature;	X
i. The words "Shake Well", "Do not Freeze" or the equivalent, as well as other instructions, when indicated by the character of the product;	X
j. The recommended individual dose, for multiple dose containers.	Single-Patient = 10 mL Contains 25
k. The route of administration recommended, or reference to such directions in an enclosed circular	X
l. Known sensitizing substances, or reference to an enclosed circular containing appropriate information;	X
m. The type and calculated amount of antibiotics added during manufacture;	X
n. The inactive ingredients when a safety factor, or reference to an enclosed circular containing appropriate information;	X
o. The adjuvant, if present;	N/A
p. The source of the product when a factor in safe administration;	X
q. The 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	X
r. 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."	X
s. The statement: "'Rx only'" for prescription biologicals.	X

JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	Checked items "x" indicate compliance
9. Barcode & Linear or One-Dimensional (1D) (Parallel Lines) NDC c. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes (to check the sponsor's NDC) b. Click "Open" c. Click "ndc_hric_labeler_codes" d. Click "Yes" e. Locate the Firm Name and the NDC Labeler Code will be to the right	X X X X X X
10. Detachable Portion If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode) The actual detach label needs to include: a. Proprietary Name b. NDC # c. Lot # & Expiry Date	N/A
If the detachable label cannot contain all the above information, then it should have: a. Proprietary Name b. NDC # c. Lot # For 2D Barcodes on the carton label to meet the regulations for the Drug Supply Chain Security Act (DSCSA). Product Identifier - 2D Barcode c. Locate the symbol and the datamatrix codes will consist of: NDC (01): EXPIRY (17): BATCH/LOT (10): SERIAL (21):	N/A X X X X X

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use Guidance for Industry	**Checked items "x" indicate compliance**
g. Multiple-Dose h. Single-Dose i. Single-Patient-Use	x

11. *If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion.*	16 years of age and older
Comments: 0.9 Sodium Chloride Injection, USP Contains 25 (KZOO & PUURS) This label is acceptable for approval.	

Appendix 8: Review Checklist for Multiple-Dose (195 Doses) Vial Carton Label: (Package) Label (NDC 0069-1000-02) submitted on August 13, 2021; August 17, 2021; and August 19, 2021.

21 CFR 610.61 (a) through (s)	Checked items "x" indicate compliance
a. The proper name of the product;	X
b. The name, address, and license number of manufacturer;	X
c. The lot number or other lot identification;	X
d. The expiration date;	X
e. The 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";	X
f. The number of containers, if more than one;	X
g. The amount of product in the container expressed as (1) the number of doses, (2) volume, (3) units of potency, (4) weight, (5) equivalent volume (for dried product to be reconstituted), or (6) such combination of the foregoing as needed for an accurate description of the contents, whichever is applicable;	X
h. The recommended storage temperature;	X
i. The words "Shake Well", "Do not Freeze" or the equivalent, as well as other instructions, when indicated by the character of the product;	X
j. The recommended individual dose, for multiple dose containers.	Single-Patient = 10 mL Contains 25
k. The route of administration recommended, or reference to such directions in an enclosed circular	X
l. Known sensitizing substances, or reference to an enclosed circular containing appropriate information;	X
m. The type and calculated amount of antibiotics added during manufacture;	X
n. The inactive ingredients when a safety factor, or reference to an enclosed circular containing appropriate information;	X
o. The adjuvant, if present;	N/A
p. The source of the product when a factor in safe administration;	X
q. The 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	X
r. 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."	X
s. The statement: "'Rx only'" for prescription biologicals.	X

JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	Checked items "x" indicate compliance
9. Barcode & Linear or One-Dimensional (1D) (Parallel Lines) NDC d. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes (to check the sponsor's NDC) b. Click "Open" c. Click "ndc_hric_labeler_codes" d. Click "Yes" e. Locate the Firm Name and the NDC Labeler Code will be to the right	X X X X X X
10. Detachable Portion If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode) The actual detach label needs to include: a. Proprietary Name b. NDC # c. Lot # & Expiry Date	N/A
If the detachable label cannot contain all the above information, then it should have: a. Proprietary Name b. NDC # c. Lot # For 2D Barcodes on the carton label to meet the regulations for the Drug Supply Chain Security Act (DSCSA). Product Identifier - 2D Barcode d. Locate the symbol and the datamatrix codes will consist of: NDC (01): EXPIRY (17): BATCH/LOT (10): SERIAL (21):	N/A X X X X X

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use Guidance for Industry	**Checked items "x" indicate compliance**
j. Multiple-Dose k. Single-Dose l. Single-Patient-Use	x

11. *If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion.*	16 years of age and older
Comments: Multiple-Dose (195 Doses) Vial Carton (KZOO & PUURS). This label is acceptable for approval.	

Appendix 9: Review Checklist for Single-Dose 0.25 mL Syringe Container Label (NDC 0069-1000-01) submitted August 13, 2021; August 17, 2021; and August 19, 2021.

21 CFR 610.60(a)(1) through (7)	Checked items "x" indicate compliance
e. *Full label.* The following items shall appear on the label affixed to each container of a product capable of bearing a full label:	X
* 1. The proper name of the product;	X
* 2. The name, address, and license number of manufacturer;	X
* 3. The lot number or other lot identification;	X
* 4. The expiration date;	X
* 5. The recommended individual dose, for multiple dose containers.	Single Dose = .25 mL
* 6. The statement: "'Rx only'" for prescription biologicals.	X
7. If a Medication Guide is required under part 208 of this chapter, the statement required under §208.24(d) of this chapter instructing the authorized dispenser to provide a 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.	N/A

21 CFR 610.62 (7) (b) through (e)	Checked items "x" indicate compliance
b. *Package label information.* If the container is not enclosed in a package, all the items required for a package label shall appear on the container label.	N/A
c. *Partial label.* If the container is capable of bearing only a partial label, the container shall show as a minimum the name (expressed either as the proper or common name), the lot number or other lot identification and the name of the manufacturer; in addition, for multiple dose containers, the recommended individual dose. Containers bearing partial labels shall be placed in a package which bears all the items required for a package label.	X
d. *No container label.* 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.	N/A
e. *Visual inspection.* 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.	X

JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	
*8. Barcode Linear or One-Dimensional (1D) (Parallel Lines) NDC e. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes (to check the sponsor's NDC) b. Click "Open" c. Click "ndc_nhric_labeler_codes" d. Click "Yes" e. Locate the Firm Name and the NDC Labeler Code will be to the right	N/A N/A
*9. Product Identifier - 2D Barcode a. Locate the symbol and the datamatrix code information will consist of: NDC (01): EXPIRY (17): BATCH/LOT (10): SERIAL (21):	N/A
10. Detachable Portion If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode) The actual detach label needs to include: a. Proprietary Name b. NDC # c. Lot # & Expiry Date If the detachable label cannot contain all the above information, then it should have: a. Proprietary Name b. NDC # c. Lot #	N/A N/A

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use Guidance for Industry	**Checked items "x" indicate compliance**
m. Multiple-Dose n. Single-Dose o. Single-Patient-Use	x

11. *If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion.*	16 years of age and older
Comments: Single-Dose 0.25 mL Syringe Container Label (KZOO & PUURS) This label is acceptable for approval.	

**** Minimum requirement for partial labels***