CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761458Orig1s000

PRODUCT QUALITY REVIEW(S)

LABELS AND LABELING ASSESSMENT

Date of Assessment:	December 12, 2025
Assessor:	Diana Pei, PharmD Labeling Assessor Office of Product Quality Assessment III (OPQA III)
Through:	Alexander Sohr, PhD Product Quality Assessor OPQA III/Division of Product Quality Assessment XIV
Application:	BLA 761458
Applicant:	GlaxoSmithKline LLC
Submission Date:	December 13, 2024
Product:	EXDENSUR (depemokimab-ulaa)
Dosage form(s):	Injection
Strength and Container-Closure:	100 mg/mL single-dose pre-filled pen 100 mg/mL single-dose pre-filled syringe with needle guard
Purpose of assessment:	The Applicant submitted a biologics license application to seek approval of EXDENSUR (depemokimab-ulaa) indicated for add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients aged 12 years and older.
Recommendations:	The prescribing information, patient labeling, container labels, and carton labeling are acceptable from an OPQA III Labeling perspective.

Materials Considered for this Label and Labeling Assessment	
Materials Assessed	**Appendix Section**
Proposed Labels and Labeling	A
Evaluation Tables	B
Acceptable Labels and Labeling	C

n/a = not applicable for this assessment

DISCUSSION

We assessed the proposed labels and labeling for compliance with applicable requirements in the Code of Federal Regulations. Also, we assessed the proposed labels and labeling for consistency with recommended labeling practices (see Appendix B).

The Applicant submitted (b) (4) in the original submission on December 16, 2024. During labeling negotiations, (b) (4) EXDENSUR (depemokimab-ulaa) will be administered by healthcare providers only. The administration instructions (b) (4) will be incorporated into the Prescribing Information.

During labeling negotiations, the (b) (4) (b) (4) was removed.

CONCLUSION

The prescribing information and patient labeling submitted on December 11, 2025 and the container labels and carton labeling submitted on November 12, 2025 were assessed and found to be acceptable (see Appendix C) from an OPQA III Labeling perspective.

APPENDICES

Appendix A: Proposed Labeling

- Prescribing Information, Patient Information, (b) (4) (submitted on December 13, 2024)
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- Container Labels (submitted on December 13, 2024)

3 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

Appendix B: Evaluation Tables
Evaluation Tables: Label[1,2] and Labeling[3] Standards

Container[4] Label Evaluation

Proper Name (container label)	Acceptable
Regulations: 21 CFR 610.60(a)(1), 21 CFR 201.10(g)(2), 21 CFR 610.62(a), 21 CFR 610.62(b), 21 CFR 610.62(c), 21 CFR 610.60(c), 21 CFR 201.50(b), 21 CFR 201.10(a), 21 CFR 201.10(i), 21 CFR 600.3(k)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices (placement of dosage form outside of parenthesis and/or below the proper name)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Manufacturer name, address, and license number (container label)	Acceptable
Regulations: 21 CFR 610.60(a)(2), 21 CFR 201.1(a), 21 CFR 610.60(c), 21 CFR 201.10(i), 21 CFR 201.100(e)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices (using the qualifying phrase "Manufactured by:")	✓ Yes ☐ No ☐ N/A
Recommended labeling practices (U.S license number for container bearing a partial label[5])	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:
For biologic products, the Applicant's name as listed in field 2 of Form FDA 356h is the name of the person or legal entity to whom the license is issued. Ensure that the manufacturer name and address appear exactly as intended for the US license holder. On the 100 mg syringe container label, revise the manufacturer's name from "GSK" to "GlaxoSmithKline LLC".

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[1] Per 21 CFR 1.3(b) *Label* means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.
[2] Per CFR 600.3(dd) *Label* means any written, printed, or graphic matter on the container or package or any such matter clearly visible through the immediate carton, receptacle, or wrapper.
[3] Per 21 CFR 1.3(a) *Labeling* includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.
[4] Per 21 CFR 600.3(bb) *Container* (referred to also as "final container") is the immediate unit, bottle, vial, ampule, tube, or other receptacle containing the product as distributed for sale, barter, or exchange.
[5] Per 21 CFR 610.60(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."

If spacing is an issue, consider removing "Mfd. by" and "Rx Only" as the label is small and could be considered a partial label and are not required per 21 CFR 610.60(c).
The Applicant revised as recommended.

The 100 mg syringe label is small and could be considered a partial label. Thus, the U.S. license number is not required per 21 CFR 610.60(c).

For the 100 mg pen label, consider adding the U.S. license number to appear under the manufacturer's name. Historical practice has been to include the U.S license number with the manufacturer's information, even for container capable of only bearing a partial label.
The Applicant revised as recommended.

Note the applicant does not have a U.S. License number so the labeling contains a placeholder, xxxx. The U.S. License number will be issued at the time of the licensure of the BLA.

Lot number or other lot identification (container label)	**Acceptable**
Regulations: 21 CFR 610.60(a)(3), 21 CFR 610.60(c), 21 CFR 201.18, 21 CFR 201.100(b)(6), 21 CFR 201.10(i)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Expiration date (container label)	**Acceptable**
Regulations: 21 CFR 610.60(a)(4), 21 CFR 201.17	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: USP General Chapters <7> Labeling, Guidance for Industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Beyond Use Date (Multiple-dose containers) (container label)	**Acceptable**
Recommended labeling practices: USP General Chapters: <659> Packaging and Storage Requirements and <7> Labeling	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

Product Strength (container label)	**Acceptable**
Regulations: 21 CFR 201.10(d)(1), 21 CFR 201.100(b)(4)	✓ Yes

	☐ No ☐ N/A
Recommended labeling practices (expression of strength for injectable drugs) references: Guidance for Industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022) *USP General Chapters: <7> Labeling*	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Multiple-dose containers (container label)	**Acceptable**
Regulations: 21 CFR 610.60(a)(5), 21 CFR 201.55 *(recommended individual dose)*	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

Statement: "Rx only" (container label)	**Acceptable**
Regulations: 21 CFR 610.60(a)(6), 21 CFR 201.100(b)(1)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices (prominence of Rx Only statement) reference: Guidance for Industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:
Due to spacing on the 100 mg syringe container label, the Applicant was recommended to remove the "Rx Only" statement to ensure the manufacturer's name has space. The label is small and could be considered a partial label. Thus, a "Rx only" statement is not required per 21 CFR 610.60(c).
The Applicant revised as recommended.

For the 100 mg prefilled pen, consider removing the bolding of Rx Only to allow for prominence of other critical information on the PDP.
The Applicant revised as recommended.

Medication Guide (container label)	**Acceptable**
Regulations: 21 CFR 610.60(a)(7), 21 CFR 208.24(d)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation: The product does not need a Medication Guide.

No Package for container (container label)	**Acceptable**
Regulation: 21 CFR 610.60(b)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation: The container is enclosed in a package.

No container label (container label)	**Acceptable**
Regulation: 21 CFR 610.60(d)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation: The product contains a container label.

Ferrule and cap overseal *(for vials only)*	**Acceptable**
Recommended labeling practices references: United States Pharmacopeia (USP) General Chapters: <7> Labeling (Ferrules and Cap Overseals)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

Visual inspection	**Acceptable**
Regulation: 21 CFR 610.60(e)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:
Confirm that sufficient area of the container remains uncovered for its full length or circumference to allow for visual inspection when the label is affixed to the container and indicate where the visual area of inspection is located.

The Applicant's response:
For the Autoinjector (AI), a wrap-around label is applied to the device housing, completely clear of the inspection window, allowing for visual inspection of the liquid drug product. The position of the label is indicated in the diagram below in blue. The inspection window can be clearly seen to the left of this, and unimpacted by the label.

Figure 1 Diagram of AI label position

The Safety Syringe Device (SSD) needle guard body is made of transparent plastic. The device labels, for front and back, are applied to two of the four faces of the SSD needle guard body. Inspection of the liquid drug product is therefore possible by looking at either of the sides of the SSD needle guard which are not covered by the labels.

Figure 2 Image of SSD showing label position

Route of administration (container label)	**Acceptable**
Regulations: 21 CFR 201.5(f), 21 CFR 201.100(b)(3), 21 CFR 201.100(d)(1)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices (route of administration statement to appear after the strength statement on the principal display panel)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:
The 100 mg syringe container label is small and would be considered a partial label so a route of administration is not required. For the 100 mg prefilled pen, relocate the route of administration to appear below the proper name and dosage form. *The Applicant revised as recommended.*

NDC numbers **(container label)**	**Acceptable**
Regulations: 21 CFR 201.2, 21 CFR 207.35	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:
The 100 mg syringe container label is small and would be considered a partial label so a NDC is not required.

Preparation instructions (container label)	**Acceptable**
Regulation: 21 CFR 201.5(g)	☐ Yes ☐ No ☒ N/A
Recommended labeling practices: Guidance for Industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

Package type term (container label)	**Acceptable**
Recommended labeling practices: 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* (October 2018) *USP chapter <659> Packaging and Storage Requirements*	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:
The 100 mg syringe container label is small and would be considered a partial label so a package type term is not required.

No misleading statements (container label)	**Acceptable**
Regulation: 21 CFR 201.6	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Prominence of required label statements (container label)	**Acceptable**
Regulation: 21 CFR 201.15	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Spanish-language (Drugs) (container label)	**Acceptable**
Regulation: 21 CFR 201.16	☐ Yes ☐ No ☒ N/A

Comment/Recommendation: The label does not display text in Spanish.

FD&C Yellow No. 5 and/or FD&C Yellow No. 6 (container label)	**Acceptable**
Regulation: 21 CFR 201.20	☐ Yes ☐ No ☒ N/A

Comment/Recommendation: The drug product does not contain FD&C Yellow No. 5 or 6.

Bar code label requirements (container label)	**Acceptable**
Regulations: 21 CFR 201.25, 21 CFR 610.67	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: Guidance for Industry *Bar Code Label Requirements Questions and Answers* (August 2011) Guidance for Industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Strategic National Stockpile (exceptions or alternatives to labeling requirements for human drug products) (container label)	**Acceptable**
Regulations: 21 CFR 610.68, 21 CFR 201.26	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

Net quantity (container label)	**Acceptable**
Regulation: 21 CFR 201.51	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: Guidance for Industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022) Guidance for Industry *Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products* (June 2015) *USP General Chapters <1151> Pharmaceutical Dosage Forms (Excess volume in injections).*	✓ Yes ☐ No ☐ N/A

Comment/Recommendation: The 100 mg syringe container label is small and would be considered a partial label so a net quantity is not required.

Statement of Dosage (container label)	**Acceptable**
Regulations: 21 CFR 610.60(a)(5), 21 CFR 610.60(c), 21 CFR 201.55, 21 CFR 201.100(b)(2)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation: The label is small and could be considered a partial label. Thus, a dosage statement is not required.

Inactive ingredients (container label)	**Acceptable**
Regulation: 21 CFR 201.100, FD&C Act section 502(e)	☐ Yes ☐ No ☒ N/A
Recommended labeling practices reference: USP General Chapters <1091> Labeling of Inactive Ingredients and USP General Chapters <7> Labeling	☐ Yes ☐ No ☒ N/A

Comment/Recommendation: The label is small and could be considered a partial label. Thus, an inactive ingredient statement is not required.

Storage requirements (container label)	**Acceptable**
Recommended labeling practices references: USP General Chapters <7> Labeling, USP General Chapters <659> Packaging and Storage Requirements	☐ Yes ☐ No ☒ N/A

Comment/Recommendation: The label is small and could be considered a partial label. Thus, storage requirements are not required.

Dispensing container (container label)	**Acceptable**
Regulation: 21 CFR 201.100(b)(7)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

Package[6] Labeling Evaluation

Proper name (package labeling)	**Acceptable**
Regulations: 21 CFR 610.61(a), 21 CFR 201.50(b), 21 CFR 201.10(g)(2), 21 CFR 600.3(k)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices (placement of dosage form outside of parenthesis and/or below the proper name)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Manufacturer name, address, and license number (package labeling)	**Acceptable**
Regulations: 21 CFR 610.61(b), 21 CFR 201.1(a), 21 CFR 201.1(i), 21 CFR 201.100(e)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices (using the qualifying phrase "Manufactured by:")	✓ Yes ☐ No ☐ N/A

Comment/Recommendation: Note the applicant does not have a U.S. License number so the labeling contains a placeholder, xxxx. The U.S. License number will be issued at the time of the licensure of the BLA.

Lot number or other lot identification (package labeling)	**Acceptable**
Regulation: 21 CFR 610.61(c), 21 CFR 201.18	✓ Yes

[6] Per 21 CFR 600.3(cc) *Package* means the immediate carton, receptacle, or wrapper, including all labeling matter therein and thereon, and the contents of the one or more enclosed containers. If no package, as defined in the preceding sentence, is used, the container shall be deemed to be the package. Thus, this includes the carton, prescribing information, and patient labeling.

	☐ No ☐ N/A

Comment/Recommendation:

Expiration date (package labeling)	**Acceptable**
Regulations: 21 CFR 610.61(d), 21 CFR 201.17	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Beyond Use Date (Multiple-dose containers) (package labeling)	**Acceptable**
Recommended labeling practices: USP General Chapters: <659> Packaging and Storage Requirements and <7> Labeling	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

Preservative (package labeling)	**Acceptable**
Regulation: 21 CFR 610.61(e)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Number of containers (package labeling)	**Acceptable**
Regulation: 21 CFR 610.61(f)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Product Strength (package labeling)	**Acceptable**
Regulations: 21 CFR 610.61(g), 21 CFR 201.10(d)(1), 21 CFR 201.100(b)(4)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: Guidance for Industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022) *USP General Chapters: <7> Labeling*	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Storage temperature/requirements (package labeling)	**Acceptable**
Regulation: 21 CFR 610.61(h)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices reference: USP General Chapters: <7> Labeling, USP General Chapters <659> Packaging and Storage Requirements	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Handling: "Do Not Shake", "Do not Freeze" or equivalent (package labeling)	**Acceptable**
Regulation: 21 CFR 610.61(i)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Multiple dose containers (recommended individual dose) (package labeling)	**Acceptable**
Regulation: 21 CFR 610.61(j)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

Route of administration (package labeling)	**Acceptable**
Regulations: 21 CFR 610.61(k), 21 CFR 201.5(f), 21 CFR 201.100(d)(1)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices (route of administration statement to appear after the strength statement on the principal display panel)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation: Relocate the route of administration so that it appears directly below the strength statement on the principal display panel. EXDENSUR

(depemokimab-xxxx)
Injection
100 mg/mL
For subcutaneous use (b) (4)
The Applicant revised as recommended.

Known sensitizing substances (package labeling)	**Acceptable**
Regulations: 21 CFR 610.61(l), 21 CFR 801.437 (User labeling for devices that contain natural rubber)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation: The product is not made with latex (natural rubber latex, dry natural rubber or synthetic derivatives of natural rubber latex).

(b) (4)

Inactive ingredients (package labeling)	**Acceptable**
Regulations: 21 CFR 610.61, 21 CFR 201.100, FD&C Act section 502(e)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: USP General Chapters <1091> Labeling of Inactive Ingredients, USP General Chapters <7> Labeling	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:
Revise the inactive ingredients to their compendial names. To ensure that all FDA approved labeling fulfills the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 502(e) revise the inactive ingredient list by using established names for drugs (i.e., drug products and ingredients). The established names for inactive ingredients in your products are the USP/NF monographs titles: arginine HCl (8.43 mg), edetate disodium (0.017 mg), histidine (1.41 mg), L-histidine HCl monohydrate (2.29 mg), polysorbate 80 (0.20 mg), trehalose (61.6 (b) (4) mg), and Water for Injection.

The Applicant's response:
GSK suggests revising the inactive ingredients as listed below.

(b) (4) *arginine HCl (8.43 mg), edetate disodium* (b) (4) *istidine (1.41 mg), L-histidine HCl monohydrate (2.29 mg), polysorbate 80 (0.20 mg), trehalose dihydrate (68.1 mg), and Water for Injection with a pH of 6.0.*

Inactive ingredients (b) (4) *and trehalose dihydrate* (b) (4) *re listed under their monograph titles, edetate disodium and trehalose*

respectively. [redacted]

GSK commits to updating Section 11 in the US PI during the first round of US PI labelling comments accordingly to read: Each 1 mL delivers 100 mg depemokimab-xxxx [redacted]arginine HCl (8.43 mg), edetate disodium [redacted] mg), [redacted]histidine (1.41 mg), Lhistidine HCl monohydrate (2.29 mg), polysorbate 80 (0.20 mg), trehalose dihydrate (68.1 mg), and Water for Injection with a pH 6.0.

Response back to Applicant:
Edetate disodium, histidine, arginine HCl, and trehalose are the official USP monographs title. Therefore, use the established names for excipients in your product as this would fulfill the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 502(e).

Confirm if disodium edetate [redacted] and trehalose dihydrate meets the definition of the USP monographs. If so, then the name and the calculated amount [redacted] will need to be revised accordingly.

Confirm the provided calculation and provide an updated Description and Composition Table in section 3.2.P.1 adding a footnote to Table 1 that includes the calculation between mg of [redacted] and mg of [redacted] The footnote should serve as a link between the name and quantity presented in section 3.2.P.1 (i.e., disodium edetate [redacted] and trehalose dihydrate) to the name and quality presented in the Prescribing Information, container label, and carton labeling (i.e., edetate disodium and trehalose).

The statement should appear as: "Each single-dose, 1-mL, prefilled pen delivers 100 mg depemokimab-xxxx, arginine HCl (8.43 mg), edetate disodium (0.017 mg), histidine (1.41 mg), L-histidine HCl monohydrate (2.29 mg), polysorbate 80 (0.20 mg), trehalose (61.6 [redacted] mg), and Water for Injection with a pH 6.0."

The Applicant revised as recommended.

Source of the product (package labeling)	**Acceptable**
Regulation: 21 CFR 610.61(p)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

Minimum potency of product (package labeling)	**Acceptable**
Regulation: 21 CFR 610.61(r)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:
Based on CDER's current interpretation of 21 CFR 610.61(r) and after consultation with OPQA III Product Quality assessors, this regulation does not apply to this product because 1) no U.S. standard of potency has been prescribed for depemokimab products (i.e., there is no specific test method described in regulation for depemokimab products that establishes an official standard of potency) and 2) Product Quality assessors have determined that potency is not a factor within the meaning of § 610.61(r) for Exdensur because lot variability is not a concern as the manufacturing process is appropriately controlled to ensure the consistency and quality of the final product. Accordingly, the phrase "No U.S. standard of potency" is not required to appear on the carton labeling. The applicant did not propose to include a "No U.S. standard of potency" statement on the carton. Thus, no comment will be sent to the applicant.

Rx only (package labeling)	**Acceptable**
Regulations: 21 CFR 610.61(s), 21 CFR 201.100(b)(1)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: Guidance for Industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Divided manufacturing (package labeling)	**Acceptable**
Regulation: 21 CFR 610.63 (Divided manufacturing responsibility to be shown) (Also refer to the Guidance for Industry, Cooperative Manufacturing Arrangements for Licensed Biologics)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

Distributor (package labeling)	**Acceptable**
Regulation: 21 CFR 610.64, 21 CFR 201.1(h)(5)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Bar code (package labeling)	**Acceptable**
Regulations: 21 CFR 610.67, 21 CFR 201.25	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: Guidance for Industry *Bar Code Label Requirements Questions and Answers* (August 2011) Guidance for Industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Strategic National Stockpile (exceptions or alternatives to labeling requirements for human drug products) (package labeling)	**Acceptable**
Regulations: 21 CFR 610.68, 21 CFR 201.26	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

NDC numbers (package labeling)	**Acceptable**
Regulations: 21 CFR 201.2, 21 CFR 207.35	✓ Yes ☐ No ☐ N/A

Comment/Recommendation: Relocate the NDC to appear in the upper right hand corner of the principal display panel. *The Applicant revised as recommended.*

Preparation instructions (package labeling)	**Acceptable**
Regulation: 21 CFR 201.5(g) and 21 CFR 610.61(i)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: Guidance for Industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022) *USP General Chapters <7> Labeling*	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Package type term (package labeling)	**Acceptable**
Recommended labeling practices: 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* (October 2018) *USP chapter <659> Packaging and Storage Requirements*	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

No misleading statements (package labeling)	**Acceptable**
Regulation: 21 CFR 201.6	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Prominence of required label statements (package labeling)	**Acceptable**
Regulation: 21 CFR 201.15	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Spanish-language (Drugs) (package labeling)	**Acceptable**
Regulation: 21 CFR 201.16	☐ Yes ☐ No ☒ N/A

Comment/Recommendation: The label does not display text in Spanish.

FD&C Yellow No. 5 and/or FD&C Yellow No. 6 (package labeling)	**Acceptable**
Regulation: 21 CFR 201.20	☐ Yes ☐ No ☒ N/A

Comment/Recommendation: The drug product does not contain FD&C Yellow No. 5 or 6.

Phenylalanine as a component of aspartame (package labeling)	**Acceptable**
Regulation: 21 CFR 201.21(c)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation: The drug product does not contain phenylalanine.

Sulfites; required warning statements (package labeling)	**Acceptable**
Regulation: 21 CFR 201.22(b)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation: The drug product does not contain sulfites.

Net quantity (package labeling)	**Acceptable**
Regulation: 21 CFR 201.51	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: Guidance for Industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022) Guidance for Industry *Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products* (June 2015) *USP General Chapters <1151> Pharmaceutical Dosage Forms (Excess volume in injections).*	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Statement of Dosage (package labeling)	**Acceptable**
Regulations: 21 CFR 201.55, 21 CFR 201.100(b)(2)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Dispensing container (package labeling)	**Acceptable**
Regulation: 21 CFR 201.100(b)(7)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

Medication Guide (package labeling)	**Acceptable**
Regulations: 21 CFR 610.60(a)(7), 21 CFR 208.24(d)	☐ Yes ☐ No

	☒ N/A

Comment/Recommendation:

Other (package labeling)	**Acceptable**
	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

Prescribing Information Evaluation

PRESCRIBING INFORMATION

Highlights of Prescribing Information	
PRODUCT TITLE	**Acceptable**
Regulation: 21 CFR 201.57(a)(2)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices reference: Draft Guidance for Industry on Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products - Content and Format (January 2018), which, when finalized, will represent FDA's current thinking on topic	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Highlights of Prescribing Information	
DOSAGE AND ADMINISTRATION	**Acceptable**
Recommended labeling practices reference: USP nomenclature for diluents and intravenous solutions	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Highlights of Prescribing Information	
DOSAGE FORMS AND STRENGTHS	**Acceptable**
Regulations: 21 CFR 201.57(a)(8), 21 CFR 201.10, 21 CFR 201.100	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: Guidance for Industry *Selection of the Appropriate Package Type Terms and Recommendations for Labeling*	✓ Yes ☐ No

Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use (October 2018) *USP chapter <659> Packaging and Storage Requirements* *USP General Chapters: <7> Labeling*	☐ N/A

Comment/Recommendation:

Full Prescribing Information	
2 DOSAGE AND ADMINISTRATION	**Acceptable**
Regulation: 21 CFR 201.57(c)(3)(iv) *Confirm appropriateness of specific direction on dilution, preparation, and administration of the dosage form and storage conditions for stability of the reconstituted or diluted drug; ensure verbatim statement for parenterals: "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit."*	✓ Yes ☐ No ☐ N/A
Recommended labeling practices reference: USP nomenclature for diluents and intravenous solutions and storage instructions for reconstituted and diluted products; confirm the appropriateness of infusion bags, infusion sets (e.g., tubing, infusion aids, or filter membranes) incompatibilities with these components Draft Guidance *Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products - Content and Format Guidance for Industry* (January 2023)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:
We revised to the following verbatim statement for parenterals: "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit." per 21 CFR 201.57(c)(3)(iv).

(b) (4)

The Applicant revised as recommended.

Comment to Applicant on the revisions sent on November 28, 2025:
Delete the air bubble statement, as no data or manufacturing process controls have been provided to support the presence (b) (4).

(b) (4)

The Applicant's response on December 9, 2025:

GSK has proposed to retain the statemen [redacted] *As noted in 3.2.P.2.3.1 Pharmaceutical Development Manufacturing Process Development, Section 3.1.7.4* [redacted] *a small residual bubble is expected. This may lead some users to prime the device during preparation, resulting in minimal dose loss.*

Comment to Applicant sent on December 11, 2025: Based on the description in P.2.3., the sentenced was revised from [redacted] to "an air bubble". [redacted]

[redacted]

The Applicant revised as recommended on December 11, 2025.

Full Prescribing Information	
3 DOSAGE FORMS AND STRENGTHS	**Acceptable**
Regulation: 21 CFR 201.57(c)(4)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: 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* (October 2018) *USP chapter <659> Packaging and Storage Requirements* *USP General Chapters: <7> Labeling*	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

Full Prescribing Information	
11 DESCRIPTION	**Acceptable**
Regulations: 21 CFR 201.57(c)(12), 21 CFR 610.61 (m), 21 CFR 610.61(o), 21 CFR 610.61 (p), 21 CFR 610.61 (q), FD&C Act Section 502(e)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: USP General Chapters <1091>, USP General Chapters <7>	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:
The pharmacological class was revised to align with the terminology used in the Highlights section.

To ensure that all FDA approved labeling fulfills the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 502(e) revise the inactive ingredient list by using established names for drugs (i.e., drug products and ingredients). The established names for inactive ingredients in your products are the USP/NF monographs titles: arginine HCl, edetate disodium, histidine, L-histidine HCl monohydrate, polysorbate 80, trehalose, and Water for Injection.

Confirm if disodium edetate (b) (4) and trehalose dihydrate meets the definition of the USP monographs. If so, then the name and the calculated amount (b) (4) will need to be revised accordingly.
Confirm the provided calculation and provide an updated Description and Composition Table in section 3.2.P.1 adding a footnote to Table 1 that includes the calculation between mg of (b) (4) and mg of (b) (4) The footnote should serve as a link between the name and quantity presented in section 3.2.P.1 (i.e., disodium edetate (b) (4) and trehalose dihydrate) to the name and quality presented in the Prescribing Information, container label, and carton labeling (i.e., edetate disodium and trehalose).

Information on (b) (4) is not required in Section 11. Thus, the information was deleted. This information is stated in Section 16.

(b) (4)

The Applicant revised as recommended.

Full Prescribing Information	
15 & 16 Hazardous Drug	**Acceptable**
Regulation: 21 CFR 201.57(c)(17)(iv) Section 15:	☐ Yes ☐ No ☒ N/A

References 1. OSHA Hazardous Drugs. OSHA. *http://www.osha.gov/SLTC/hazardousdrugs/index.html* Section 16: xxxx is a hazardous drug. Follow applicable special handling and disposal procedures.[1]	

Comment/Recommendation:

Full Prescribing Information	
16 HOW SUPPLIED/ STORAGE AND HANDLING	**Acceptable**
Regulation: 21 CFR 201.57(c)(17)	✓ Yes ☐ No ☐ N/A
Recommended labeling practices: to ensure placement of detailed storage conditions for reconstituted and diluted products	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:
Revised for readability.

(b) (4)

[redacted]

The Applicant revised as recommended.

Full Prescribing Information	
MANUFACTURER INFORMATION	**Acceptable**
Regulations: 21 CFR 201.100(e), 21 CFR 201.1	✓ Yes ☐ No ☐ N/A
Recommended labeling practices references: 21 CFR 610.61(b) (add the US license number for consistency with the carton labeling), and 21 CFR 610.64 (Name and address of distributor may appear and use a qualifying phrase for consistency with the carton labeling, when applicable)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:
The manufacturer's street address has been added to the manufacturer's information for completeness of the information.

Note the applicant does not have a U.S. License number so the labeling contains a placeholder, xxxx. The U.S. License number will be issued at the time of the licensure of the BLA.

Patient Information Labeling Evaluation

PATIENT INFORMATION LABELING	
TITLE (NAMES AND DOSAGE FORM)	**Acceptable**
Recommended Labeling Practices references: To ensure consistency with the product title in the Highlights of Prescribing Information (see Draft Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products - Content and Format Guidance for Industry (January 2018). For the recommended dosage form (see USP General Chapters: <1> Injections, Nomenclature and Definitions, Nomenclature form).	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

PATIENT INFORMATION LABELING	
STORAGE AND HANDLING	**Acceptable**
Recommended labeling practices for Patient Labeling: To ensure that applicable storage and handling requirements are consistent with the information provided in the PI (Reference: Section 2 (Dosage and Administration) and Section 16 (How Supplied Storage and Handling) of the PI)	☐ Yes ☐ No ☒ N/A

Comment/Recommendation:

PATIENT INFORMATION LABELING	
INGREDIENTS	**Acceptable**

Recommended labeling practice: To ensure labeling of inactive ingredients are in alphabetical order (see USP General Chapters <1091>)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:
To ensure that all FDA approved labeling fulfills the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 502(e) revise the inactive ingredient list by using established names for drugs (i.e., drug products and ingredients). The established names for inactive ingredients in your products are the USP/NF monographs titles: arginine HCl, edetate disodium, histidine, L-histidine HCl monohydrate, polysorbate 80, trehalose, and Water for Injection.

(b) (4)

Revised labeling returned on November 12, 2025:
The following revisions were made:

1) A space was added between "arginine" and 'HCl".
2) The hyphen before "histidine" was deleted.
3) The "HCL" was revised to "HCl" for L-histidine HCl monohydrate.

(b) (4)

Applicant revised as recommended in November 28, 2025 revisions.

PATIENT INFORMATION LABELING	
MANUFACTURER INFORMATION	**Acceptable**
21 CFR 201.1, 19 CFR 134.11	✓ Yes ☐ No ☐ N/A
21 CFR 610.61 (add the US license number for consistency with the carton labeling), 21 CFR 610.64 (Name and address of distributor may appear and use a qualifying phrase for consistency with the carton labeling, when applicable)	✓ Yes ☐ No ☐ N/A

Comment/Recommendation:

APPENDIX C. Acceptable Labels and Labeling
To note, additional non-product quality-related revisions may be submitted at a future date within this review cycle. Product quality-related information in this version of the labeling is acceptable from OPQA III labeling perspective.

- Prescribing Information and Patient Information (submitted on December 11, 2025)
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3 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

Diana Pei

Digitally signed by Diana Pei
Date: 12/12/2025 12:38:59PM
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Alexander Sohr

Digitally signed by Alexander Sohr
Date: 12/12/2025 12:52:44PM
GUID: 6447f8e60119df7dd30bbd3b1d5bb2e2

BLA Executive Summary
Assessment Date: December 1, 2025

1. Application/Product Information

BLA number	761458
Submission Type	Original Submission
Regulatory Pathway	351(a)
Associated IND/BLA	IND 146742
Review Designation	Standard
Applicant	GlaxoSmithKline LLC
Indication	EXDENSUR (depemokimab) is proposed for the following (b) (4): 1. Treatment of asthma (b) (4)
Rx/OTC dispensed	Rx
Drug Product Name	**Proprietary Name**: EXDENSUR
	Non-proprietary Name/Code Name: depemokimab
	OPQA III Naming: MAB HUMANIZED (IGG1) ANTI P05113 (IL5_HUMAN) [GSK3511294]
Drug Product Description	The proposed depemokimab DP strength and presentation is 100 mg/mL in a pre-filled syringe (PFS) filled to 1 mL that is housed in an autoinjector (AI) or safety syringe device (SSD) that deliver 100 mg of depemokimab subcutaneously. Depemokimab DP is formulated as 100 mg/mL depemokimab, (b) (4) mM (b) (4) histidine/ L-histidine HCl monohydrate, 40 mM (b) (4) arginine HCl, 180 mM trehalose dihydrate, (b) (4) mM disodium edetate (b) (4) and 0.02% (w/v) polysorbate 80 (PS80) at pH 6.0 in water for injection. Depemokimab DP is stored at 2-8°C, protected from light.

	Depemokimab is a recombinant [(b) (4)] humanized IgG1κ monoclonal antibody specific for human interleukin-5 (IL-5) that is produced in Chinese Hamster Ovary (CHO) cells. IL-5 is a cytokine that increases Type 2 inflammation, which is an important component in the pathogenesis of asthma [(b) (4)]. IL-5 interaction with the interleukin-5 receptor (IL-5Rα) on eosinophils leads to expansion and differentiation of eosinophils in the bone marrow, and recruitment, activation, and survival of eosinophils in the tissue space. Depemokimab binds IL-5, thereby inhibiting its bioactivity and the resultant IL-5-mediated inflammatory response. Depemokimab DS is a clear to opalescent, colorless, yellow to brown liquid, a pH of [(b) (4)] and a concentration of [(b) (4)] mg/mL. Depemokimab DS is stored at ≤ [(b) (4)] °C, [(b) (4)]		
Dosage Form	Liquid		
Strength	100 mg/mL		
Route of Administration	Subcutaneous		
Primary Container Closure System	PFS		
Device Information	The PFS is assembled in an AI or SSD		
Co-packaged Product Information	N/A		
OPQ Review Team	**Discipline**	**Primary**	**Secondary**
	Drug substance	Alex Sohr	Brian Roelofs
	Drug product		
	Immunogenicity Assay		
	PLCM		
	DS Microbiology and Facility	Olumide Martins	Madushini Dharmasena
	DP Microbiology and Facility	Michal Levine Millrod	
	RBPM	Nowrin Kakon	
	ATL	Brian Roelofs	
	Pharmaceutical Quality System - Office of Quality Surveillance (OQS)	Torrey Ward, Carla Lundi, Nyrma Cruz, Vlada Matusovsky, Catherine Tran-Zwanetz and Mary Manibusan	

OPQ Issued Consults	CDRH: ICCR# 01042516 for the device constituent SSD or AI ICCR# 01043001 for the facilities responsible for device assembly (b) (4) EC Team: Yan Wang (OPQAIII Q12 AIT) Mahesh Ramanadham (OPPQ ECCC Representative)

2. Recommendation and Conclusion on Approvability
Recommendation: Approval with PMCs/PMRs

The Office of Pharmaceutical Quality, CDER, recommends approval of BLA 761458 for EXDENSUR manufactured by GlaxoSmithKline LLC. The data submitted in this application are adequate to support the conclusion that the manufacture of EXDENSUR is well-controlled and leads to a product that is pure and potent. It is recommended that this product be approved for human use under conditions specified in the package insert.

3. CMC Information for Action Letter

a. Manufacturing Location:
- **Drug Substance:** GlaxoSmithKline LLC, Conshohocken, PA (FEI: 3004055938)
- **Drug Product:** Glaxo Operations UK Ltd, Barnard Castle, UK (FEI: 3002807078)

b. Fill size and dosage form:
The proposed depemokimab DP strength and presentation is 100 mg/mL in a pre-filled syringe (PFS) filled to 1 mL that is housed in an autoinjector (AI) or safety syringe device (SSD) that deliver 100 mg of depemokimab subcutaneously.

c. Dating Period:
- **Drug Product:** 24 months when stored at 2 to 8°C with an allowance for one week at room temperature not to exceed 30°C, protected from light.
- **Drug Substance:** (b) (4) months when stored at (b) (4) °C, (b) (4) (b) (4)
- **Stability Option:**
  - For stability protocols:
    - We have approved the stability protocol(s) in your license application for the purpose of extending the expiration

dating of your drug substance and drug product under 21 CFR 601.12.

d. Exempt from lot release:

- Yes
- Rationale, if exempted: EXDENSUR is exempted from lot release per FR 95-29960.

e. Draft Phase 4 (Post-Marketing) Commitments, Requirements, Agreements, and/or Risk Management Steps, as applicable

4920-4
Qualification of a new Working Reference Standard.
Final Report Submission date: 12/2026, Annual Report

4920-5
Conduct an additional bacterial retention study, including differential pressure monitoring and submit the final report in a CBE-30 supplement.
Final Report Submission date: 02/2026

4920-6
Repeat the CCIT validation for AI and SSD by dye ingress, revise the acceptance criteria (b) (4) as expected and submit the final report in a CBE-0 supplement.
Final Report Submission date: 01/2026

4. Basis for Recommendation

a. Summary: EXDENSUR (depemokimab, GSK3511294) is a recombinant (b) (4) humanized IgG1κ monoclonal antibody specific for human interleukin-5 (IL-5) that is produced in Chinese Hamster Ovary (CHO) cells. IL-5 is a cytokine that increases Type 2 inflammation, which is an important component in the pathogenesis of asthma (b) (4). IL-5 interaction with the interleukin-5 receptor (IL-5Rα) on eosinophils leads to expansion and differentiation of eosinophils in the bone marrow, and recruitment, activation, and survival of eosinophils in the tissue space. Additional cell types that express IL-5Rα including mast cells, plasma cells, epithelial cells, and fibroblasts are also involved in inflammation.

Depemokimab binds IL-5, thereby inhibiting its bioactivity and the resultant IL-5-mediated inflammatory response. The potency of EXDENSUR is assessed using a surface-plasmon resonance (SPR) binding assay specific for IL-5 for both the DS and DP release and stability testing and a cell-based IL-5

neutralization assay that measures the inhibition of proliferation of IL-5 dependent human bone marrow erythroleukemia cells in the DP release and stability testing.

Depemokimab DS is manufactured at GlaxoSmithKline LLC, Conshohocken, PA (FEI: 3004055938, GSK Conshohocken). The DS is a clear to opalescent, colorless, yellow to brown liquid, with pH of (b) (4), and a concentration of (b) (4) mg/mL. Depemokimab DS is stored at ≤ (b) (4) °C, (b) (4)

(b) (4)

The EXDENSUR DP manufacturing and autoinjector assembly site is Glaxo Operations UK Ltd, Barnard Castle, UK (FEI: 3002807078, Glaxo BC). EXDENSUR DP strength and presentation is 100 mg/mL in a pre-filled syringe (PFS) filled to 1 mL that is housed in an autoinjector (AI) or safety syringe device (SSD) that deliver 100 mg of depemokimab subcutaneously. The DP manufacturing process beings with (b) (4)

(b) (4)

(b) (4) The final EXDENSUR DP is stored at 2-8°C, protected from light.

The Applicant committed to conduct an additional bacterial retention study, monitoring differential pressure. (b) (4) The initial bacterial retention study did not measure differential pressure. The limits are appropriate, and the additional bacterial retention study is committed to as a PMC. The Applicant also committed to repeat the container closure integrity testing (CCIT) validation for the AI and SSD by dye ingress. The original approach included acceptance criteria (b) (4) In the PMC, the new validation will include revised acceptance criteria (b) (4)

The product lifecycle management (PLCM) document submitted with the original BLA submission contained proposed (b) (4)

A pre-license inspection of the DS manufacturing facility GSK Conshohocken was performed from February 27 to March 7, 2025. The inspection and internal compliance review of the firm's responses to the 483 items concluded with a recommendation of approve. A remote regulatory assessment (RRA) of the device assembly component of the DP manufacturing site GSK BC was performed and the outcome was a recommendation of approve with a voluntary action indicated (VAI) classification. An inspection of the DP manufacturing process component of the GSK BC site was waived based on satisfactory inspection history.

The assessment of manufacturing information provided in this application has concluded that the methodologies and processes used for DS and DP manufacturing, release, stability testing, microbial control and sterility assurance are sufficiently robust and controlled to ensure the consistent manufacture of a safe, pure, and potent product. The AI and SSD devices are approvable. The immunogenicity assays to detect and confirm anti-drug

antibodies (ADAs) against depemokimab in the clinical studies to support this BLA were adequately validated and suitable for their intended purpose.

a. Subdiscipline Recommendation:

Drug Substance	**-**	**Adequate with PMCs/PMRs**
Drug Product	**-**	**Adequate**
Immunogenicity Assay	**-**	**Adequate**
Facilities	**-**	**Adequate**
Microbiology	**-**	**Adequate with PMCs/PMRs**

b. Environmental Assessment (EA):
Categorical exclusion is claimed by the applicant and deemed acceptable.

c. Potency Assessment for Labeling:
As an initial matter, we determined that no U.S. standard of potency has been prescribed for EXDENSUR(depemokimab) (i.e., there is no specific test method described in regulation for EXDENSUR(depemokimab) that establishes an official standard of potency). We next considered whether potency is a factor for EXDENSUR(depemokimab) within the meaning of 21 CFR 610.61(r), which requires a statement about potency on the package (carton) label if "potency is a factor" and "no U.S. standard of potency has been prescribed." We have determined that potency is not a factor for EXDENSUR(depemokimab) for purposes of § 610.61(r) because lot variability is not a concern for EXDENSUR(depemokimab) as EXDENSUR(depemokimab)'s manufacturing process is appropriately controlled to ensure the consistency and quality of the final product.

5. Life-Cycle Considerations

a. Established Conditions based on ICH Q12 principles: No

b. Drug Substance:
i. Protocols approved:

- (b) (4)

ii. Residual risk: None
iii. Future inspection points to consider: None

c. Drug Product:

i. Protocols approved:

- Drug product Annual Stability Protocol (with shelf-life extension)
- Container Closure Integrity Testing (CCIT) validation protocol using a dye immersion method

ii. Residual risk:

- Refer to Section 4.a of the memo for residual risks related to an additional bacterial retention study and the CCIT validation for AI and SSD by dye ingress

iii. Future inspection points to consider: None

FOIA statement: More detailed assessments of the BLA submission, which are not included in this integrated quality assessment, may be requested via a Freedom of Information Act (FOIA) request.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

BRIAN A ROELOFS
12/01/2025 02:59:08 PM

MADUSHINI N DHARMASENA
12/01/2025 03:00:13 PM