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MEMORANDUM

Date: March 25, 2026

From: Jennifer Albert, RN, DCPM
Regulatory Project Manager
Division of Review Management and Regulatory Review 1
Office of Review Management and Regulatory Review
Office of Therapeutic Products
Center for Biologics Evaluation and Research

Through: Nadia Whitt, MS
Branch Chief
Division of Review Management and Regulatory Review 1
Office of Review Management and Regulatory Review
Office of Therapeutic Products
Center for Biologics Evaluation and Research

To: BLA 125806/0

Action Due Date: March 28, 2026

Applicant: Rocket Pharmaceuticals Inc.

Product: marnetegrane autotemcel (KRESLADI)

Subject: Review of Rocket Pharmaceuticals Inc Package (Carton) Labels, Container Labels, National Drug Code (NDC), Associate Bar Codes, and Product Identifiers

Materials Reviewed (as Applicable):

Material	Receipt Date	Amendment #	NDC numbers	Strength
Package (Carton) Cassette	Aug. 1, 2023	104	NDC 83537-034-01	30 mL containing 0.34 to 6.1 × 10 ⁶ cells/mL (0.32 to 6.1 × 10 ⁶ CD34+ cells/mL)

Material	Receipt Date	Amendment #	NDC numbers	Strength
Container Infusion Bag	Aug. 1, 2023	104	NDC 83537-034-01	30 mL containing 0.34 to 6.1 × 10 ⁶ cells/mL (0.32 to 6.1 × 10 ⁶ CD34+ cells/mL)

The applicant submitted:

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

Background:

Rocket Pharmaceuticals Inc. (Rocket) submitted BLA 125806 on August 1, 2023 for marnetegrane autotemcel (KRESLADI) for the treatment of pediatric patients with severe leukocyte adhesion deficiency-I (LAD-I) due to biallelic variants in ITGB2 without an available human leukocyte antigen (HLA)-matched sibling donor for allogeneic hematopoietic stem cell transplant.

On February 25, 2026, under section 582(a)(3)(A)(iii) of the Food Drug & Cosmetic Act (FD&C Act), Rocket Pharmaceuticals (Rocket) requested exemption for DSCSA requirements specifically from the 2D barcode requirement described under section 582(a)(9) of the FD&C Act. OCBQ/DSCSA-CBER-WEER was consulted and exemption letter for the DSCSA exemption is granted.

National Drug Code was reactivated by Rocket and was confirmed to be 83537.

Review and Communications:

The review of this product's carton and container labels include the original submission received on August 1, 2023 (seq 0001) and revisions in response to information requests received: January 14, 2026 (seq 0090) and March 23, 2026 (seq 0116).

C 910.07: Regulatory Labeling Review Checklist

<p align="center">DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH</p>
STN: BLA 125806.0.82
Manufacturer: Rocket Pharmaceuticals, Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
Diluent Manufacturer (as applicable): N/A
Product: KRESLADI (marnetegrane autotemcel)
RPM: Jennifer Albert, RN, DCPM (October 22, 2025/March 25, 2026)
BC: Nadia Whitt, MS
Clinical Reviewer: Erica Glancy
CMC Reviewer: Pankaj Mandal
APLB Reviewer: Teresa Vu

Summary of Items reviewed:

1. Package Linear Barcode (Cassette)
2. Container Linear Barcode (Infusion Bag)
3. Package Product Identifier, 2D Barcode
4. Package NDC
5. Container NDC
6. Package Review
7. Container Review

Table 1: Package Linear Barcode Review

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

Table 2: Container Linear Barcode Review

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

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

Table 3: Package 2D Barcode Review

Package Product Identifier: 2D Barcode (non-linear) review under the DSCSA	Yes/No	Comment
Applicant is requesting either a waiver, exception, or exemption (WEE) from DSCSA requirements	Yes	DSCSA waiver submitted
Applicant is granted waiver, exception, or exemption from DSCSA requirements	Yes	Grant letter will be issued with Final Letter to Rocket.
Non-linear (2D barcode) is present	No	
<p>The human-readable portion elements of the product identifier that are required under the DSCSA are present:</p> <p>NDC: [insert product's NDC] SERIAL: [insert product's serial number] LOT: [insert product's lot number] EXP: [insert product's expiration date]</p> <p>Note: If the NDC is not included with the other elements, it should be located in close proximity to the 2D barcode.</p>	Yes	<p>NDC: 83537-XXX-XX,</p> <p>LOT: XXXX-XXXXXX,</p> <p>EXP: DD-MMM-YYYY present; SERIAL not present</p>

Table 4: Package NDC Review

Package NDC	Yes/No	Comment
Labeler code (First segment of NDC) is valid	Yes	83537
Product code (second segment of NDC) is appropriate for the package	Yes	034
The product code configuration is consistent with the other NDCs (e.g., Prescribing Information (PI),)	Yes	
Package code (third segment of NDC) is appropriate for the package	Yes	01
The package code configuration is consistent with the other NDCs (e.g.,	Yes	

Package NDC	Yes/No	Comment
PI,)		
The NDC is listed in the principal display panel and/or near the 2D barcode and linear barcode, as applicable	Yes	
NDCs are consistent with the NDCs listed in section 16 HOW SUPPLIED/STORAGE AND HANDLING OF THE PI (in the SPL and Word versions)	Yes	

Table 5: Container NDC Review

Container NDC	Yes/No	Comment
Labeler code (First segment of NDC) is valid	Yes	83537
Product code (second segment of NDC) is appropriate for the container	Yes	034
The product code configuration is consistent with the other NDCs (e.g., PI)	Yes	
Package code (third segment of NDC) is appropriate for the container	Yes	01
The package code configuration is consistent with the other NDCs (e.g., PI)	Yes	
The NDC is listed in the principal display panel and/or near the 2D barcode and linear barcode, as applicable	Yes	
NDCs are consistent with the NDCs listed in section 16 HOW SUPPLIED/STORAGE AND HANDLING OF THE PI (in the SPL and Word versions)	Yes	

Note: For all tables below review package and container labeling for completeness and not for layout and accuracy. If an element is missing, notify the BLA Chair/Clinical/CMC/APLB reviewer(s).

Table 6: Package and Container Review

Package AND Container bearing a full label	Yes/No	Comment
Proper Name of the product is displayed <i>Note: 21 CFR 610.62 is not applicable to some CBER products. 21 CFR 601.2(c), does not apply to "a therapeutic DNA plasmid product, therapeutic synthetic peptide product of</i>	Yes	
Manufacturer's Name, address, and license number (or applicant's license number)	Yes	
Lot Number or other lot identification	Yes	
Expiration Date	Yes	
"Rx only" for prescription products	Yes	

Table 7: Container Review

Container Label	Yes/No	Comment
The recommended individual dose, for multiple dose containers (for single-patient use or multiple-patient use)"	Yes	Single dose product
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	
If the container is not enclosed in a package, all the items required for a package label shall appear on the container label.	No	

Container Label	Yes/No	Comment
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.	N/A	Full 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	
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.	Yes	


Table 8: Package Review

Package Label	Yes/No	Comment
Preservative used and its concentration OR if no preservative is used and the absence of a preservative is a safety factor, the words "no preservative"	Yes	"no preservative"
Number of containers, if more than one	Yes	Bag x of x
Amount of product (e.g., number of doses, volume, weight, units of potency)	Yes	30 mL containing 0.34 to 6.1×10^6 cells/mL (0.32 to 6.1×10^6 CD34+ cells/mL)
Storage Temperature	Yes	$\leq -150^\circ\text{C}$
The words "Shake Well", "Do not Freeze" or the equivalent, as well as other instructions, when indicated by the character of the product	Yes	Do not irradiate.
The recommended individual Dose if the enclosed container(s) is a multiple-dose container	Yes	

Package Label	Yes/No	Comment
Route of administration recommended, or reference to such directions in an enclosed circular	Yes	INTRAVENOUS USE ONLY
Known sensitizing substances, or reference to an enclosed circular containing appropriate information	N/A	
Type and calculated amount of antibiotics added during manufacturing	N/A	
The inactive ingredients when a safety factor, OR reference to an enclosed circular containing appropriate information;	Yes	5% DMSO
Adjuvant, if present	N/A	
The source of the product when a factor in safe administration	Yes	Genetically modified autologous hematopoietic stem cells
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	N/A	
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."	N/A	
Divided manufacturing responsibility to be shown (21 CFR 610.63) If two or more licensed manufacturers participate in the manufacture of a biological product, the name, address, and license number of each must appear on the package label, and on the label of the container if capable of bearing a full label.	N/A	
Name and address of distributor (21 CFR 610.64) The name and address of the distributor of a product may appear on the label provided that the name, address, and license number of the manufacturer also appears on the label and the name of the distributor is qualified by one of the following phrases: "Manufactured for _____",	Yes	


Package Label	Yes/No	Comment
“Distributed by _____”, “Manufactured by _____ for _____”, “Manufactured for _____ by _____”, “Distributor: _____”, or “Marketed by _____”. The qualifying phrases may be abbreviated.		

Cassette Sticker (size 108x89mm)

marnetegrane autotemcel NDC 83537-034-01 KRESLADI Suspension for IV infusion 30 mL containing 0.34 to 6.1 × 10 ⁶ cells/mL (0.32 to 6.1 × 10 ⁶ CD34+ cells/mL)	
	
FOR AUTOLOGOUS AND INTRAVENOUS USE ONLY. Rx Only	
Dosage: See Prescribing Information. See Lot Information Sheet for number of CD34+ cells per kg for this patient. Dose may be suspended in 1 or 2 infusion bag(s). Contents: Genetically modified autologous hematopoietic stem cells in a cryopreservative solution containing 5% DMSO. Store in vapor phase of liquid nitrogen (≤ -150 °C). Do not irradiate. Not evaluated for infectious substances. No Preservative. Do not use an in-line blood filter or infusion pump.	
Verify Patient ID First: FIRST NAME Last: LAST NAME DOB: DD-MMM-YYYY Rocket ID:	COI ID: DIN: XXXXX XX XXXXXX XXX XXX XXXX XXXX LOT: XXXX-XXXXXX EXP: DD-MMM-YYYY Bag X of X
Manufactured for: Rocket Pharmaceuticals, Inc. Cranbury, NJ 08512 1-800-982-2410 U.S. Lic. #XXXX	

Infusion Bag Sticker (40x48mm)

Front

marnetegrane autotemcel NDC 83537-034-01 KRESLADI Suspension for IV infusion 30 mL containing 0.34 to 6.1 × 10 ⁶ cells/mL (0.32 to 6.1 × 10 ⁶ CD34+ cells/mL)
FOR AUTOLOGOUS AND INTRAVENOUS USE ONLY. See Lot Information Sheet for number of CD34+ cells per kg for this patient. Do not irradiate. Do not use an in-line blood filter or infusion pump.

Rx Only U.S. Lic. #XXXX

Back

Verify Patient ID First: FIRST NAME Last: LAST NAME DOB: DD-MMM-YYYY Rocket ID: COI ID:
DIN: XXXXX XX XXXXXX XXX XXX XXXX XXXX LOT: XXXX-XXXXXX EXP: DD-MMM-YYYY Bag X of X
Manufactured for: Rocket Pharmaceuticals, Inc. Cranbury, NJ 08512 U.S. Lic. #XXXX

Recommendations:

This original BLA can be approved regarding NDC assignment.

	March 25, 2026
RPM	Date
<hr/>	
Branch Chief	Date