CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216632Orig1s000

PRODUCT QUALITY REVIEW(S)

Memorandum

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: **October 17, 2023**

From: **Nina Ni, Ph.D.**
Application Technical Lead, Branch 4
Division of New Drug Products 2
Office of New Drug Products

To: **To IQA Assessment of NDA 216632**

Subject: **Final ONDP Recommendation of "Approval"**

In the original IQA review dated August 7, 2023, this NDA was not recommended for approval in the form it was presented due to unresolved labeling/labels issues identified by the Drug Product Reviewer, Dr. Zhengfang Ge as per 21 CFR 314.125(b)(6). The applicant submitted revised labeling and labels on October 17, 2023. The revised labeling and labels have been reviewed by Dr. Zhengfang Ge on October 17, 2023 and found adequate to support the approval of this application from the labeling and labels perspective (see the Attachment).

Therefore, from the OPQ perspective, this NDA is recommended for **approval**.

In addition, NDA number on page 4 of the original IQA Assessment should be 216632, not (b) (4)

Zhengfang Ge, Ph.D. acting for
Nina Ni, Ph.D.
Branch 4/DNDP II/ONDP/OPQ

Labeling Review Attachment

Date: **Oct 17, 2023**

From: **Zhengfang Ge, Ph.D.**
ONDP/Division II/Branch IV

Through: **Nina Ni, Ph.D.**
Chief, ONDP/Division II/Branch IV

To: **Labeling Review of NDA 216632**

Subject: **Final Labels**

The Labeling review #1 has noted the following pending issues:

- The dosage form should be changed from (b) (4) to "topical gel" throughout the labeling and labels.

And because of this deficiency, in the Labeling Review #1, this NDA was not recommended for approval from the labeling perspective.

On Oct 17, 2023, the applicant amended the labeling and labels and the above issue is satisfactorily resolved.

Recommendation:
This NDA is **now** recommended for approval from the labeling perspective.

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/s/

ZHENGFANG GE
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RECOMMENDATION

☒ Approval Pending on Labeling
☐ Approval with Post-Marketing Commitment
☐ Complete Response

NDA 216632
Assessment 1

Drug Product Name	CABTREO™ (clindamycin phosphate/adapalene/benzoyl peroxide) topical gel
Dosage Form	Topical gel
Strength	1.2%/0.15%/3.1%
Route of Administration	For topical use
Rx/OTC Dispensed	Rx
Applicant	Bausch Health US, LLC (Bausch)
US agent, if applicable	NA

Submission(s) Assessed	Document Date	Discipline(s) Affected
Original Submission, eCTD SN 0001	12/22/2022	DS, DP, OPMA, and Micro
Amendment, SN 0002	02/02/2023	DS, DP, and OPMA
Amendment, SN 0004	04/17/2023	DP
Amendment, SN 0005	04/21/2023	Labeling
Amendment, SN 0006	05/17/2023	OPMA and Micro
Amendment, SN 0008	06/02/2023	OPMA
Amendment, SN 0010	07/21/2023	OPMA
Amendment, SN 0011	07/28/2023	OPMA

QUALITY ASSESSMENT DATA SHEET

For more details about the items in this template, please see the Quality Assessment Data Sheet chapter of the NDA IQA Guide

1. RELATED/SUPPORTING DOCUMENTS

A. DMFs:

DMF #	Type	Holder	Item Referenced	Status	Date Assessment Completed	Comments
(b) (4)	II		(b) (4)	Adequate	03/13/2023	Reviewed by F. Burnett
	II			Adequate	09/28/2022	Reviewed by W. Song
	II			Adequate	11/14/2022	Reviewed by B. Gaddam
	III			NA	NA	Adequate info provided in the NDA
	III			NA	NA	Adequate info provided in the NDA

B. OTHER DOCUMENTS: *IND, RLD, RS, Approved NDA*

Document	Application Number	Description
IND	131347	Conducted clinical studies
NDA	50819	Acanya gel and Onexton gel
NDA	50756	Benzaclin gel

2. CONSULTS

Discipline	Status	Recommendation	Date	Assessor
Biostatistics	NA			
Pharmacology/Toxicology	NA			
CDRH	NA			
Clinical	NA			
Other	NA			

NDA Executive Summary

1. Application/Product Information

NDA Number.	216632		
Applicant Name	Bausch Health US, LLC (Bausch)		
Drug Product Name	CABTREO™ (clindamycin phosphate/adapalene/benzoyl peroxide) topical gel, also coded as IDP-126		
Dosage Form.	(b) (4)		
Proposed Strength(s)	1.2%/0.15%/3.1%		
Route of Administration	Topical		
Maximum Daily Dose	(b) (4)		
Rx/OTC Dispensed	Rx		
Proposed Indication	For the treatment of people (b) (4) years of age and older with acne vulgaris		
Drug Product Description	CABTREO™ topical gel is opaque, white to off-white gel supplied as 20 and 50 g in tube or pump		
Co-packaged product information	N/A		
Device information:	N/A		
Storage Temperature/ Conditions	Store in a refrigerator, 2° to 8°C (36° to 46°F). PHARMACIST: • Dispense CABTREO with a 10-week expiration date. • Specify “Store at room temperature at or below 25°C (77°F). Do not freeze.”		
Review Team	**Discipline**	**Primary**	**Secondary**
	Drug Substance	Friedrich Burnett	Lawrence Perez
	Drug Product/ Labeling	Zhengfang Ge	Nina Ni

	Manufacturing	Khalid Khan	Cassandra Abellard
	Biopharmaceutics	N/A	N/A
	Microbiology	Koushik Paul	Jesse Wells
	Other (specify):	N/A	N/A
	RBPM	Grafton Adams/Rajani Ranga	
	ATL	Nina Ni	
Consults	N/A		

2. Final Overall Recommendation - Approval, see additional comment

3. Action Letter Information

a. Expiration Dating: 21 months

b. Additional Comments for Action OPQ recommends approval once labeling negotiation is complete.

4. Basis for Recommendation:

a. Summary of Rationale for Recommendation:

OPQ recommends APPROVAL of NDA (b) (4) for commercialization of CABTREO™ (clindamycin phosphate/adapalene/benzoyl peroxide) topical gel, 1.2%/0.15%/3.1% once the labeling negotiation is complete.

Based on our evaluation of the available information, the applicant provided sufficient information to support an approval recommendation from the product quality perspective. The applicant provided adequate chemistry, manufacturing, and controls (CMC) information to ensure the identity, strength, purity, and quality of the proposed drug product. The overall manufacturing inspection recommendation is approval for all the facilities associated with this application. The comments to the proposed labeling and

labels have been communicated to the review team. Once revision received from the applicant, the proposed labeling and labels should include adequate information to meet the regulatory requirements.

b. Is the overall recommendation in agreement with the individual discipline recommendations? Yes

Recommendation by Subdiscipline:

Drug Substance	**-**	**Adequate**
Drug Product	**-**	**Adequate**
Quality Labeling	**-**	**Pending**
Manufacturing	**-**	**Adequate**
Biopharmaceutics	**-**	**Adequate**
Microbiology	**-**	**Adequate**

Environmental Assessment: Categorical Exclusion - Adequate
QPA for EA(s): Yes

5. Life-Cycle Considerations

Established Conditions per ICH Q12: No
Comments: N/A

Comparability Protocols (PACMP): No
Comments: N/A

Additional Lifecycle Comments:

Manufacturing and facility review team recommends a post-approval inspection for Bausch Health Companies Inc. (FEI: 3002807186). The site is mainly responsible for manufacturing, packaging, release and stability testing, and microbiological testing for drug product. Refer to this review of Chapter V below for details.

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CHAPTER VII: MICROBIOLOGY

IQA ANDA Assessment Guide Reference

Product Information	For treatment of acne vulgaris.
NDA Number	216632
Assessment Cycle Number	MR01
Drug Product Name / Strength	clindamycin phosphate / adapalene / benzoyl peroxide (CABTREO; 1.2% / 0.15% / 3.1%).
Route of Administration	Topical Gel
Applicant Name	Bausch Health US, LLC.
Method of Sterilization	Non-Sterile.

Assessment Recommendation: **Adequate**

Theme:

☒ N/A	☐ Depyrogenation Validation Data
☐ Product Sterility Assurance	☐ Product Release and/or Stability Specifications
☐ Media Fill Data	☐ Validation for Product Release and/or Stability Test Method
☐ Validation of Product Test	☐ Other (Requires Division Director Approval)
☐ Due to Consult	

Justification: *view justification statements found at:* **Justification Statements**

N/A
Other (Requires Division Director Approval) – *Assessor writes-in justification here if "other" selected as theme.*

Assessment Summary: (b) (4)

List Submissions Being Assessed (table):

Document(s) Assessed	Date Received
eCTD Seq #0006	05/17/2023
eCTD Seq #0001	12/22/2022

Highlight Key Issues from Last Cycle and Their Resolution: N/A

Remarks: The submission is **recommended** for approval on the basis of sterility assurance.

Concise Description of Outstanding Issues: None.

Supporting Documents: None.

Select Number of Approved Comparability Protocols: 0

P.1 Description of the Composition of the Drug Product

Description of the Composition of the Drug Product

(*3.2.P.1 description-and-composition.pdf)*

The IDP-126 (1.2% clindamycin phosphate/0.15% adapalene/3.1% benzoyl peroxide) is white to off-white, opaque, (b) (4) gel indicated for topical administration for the treatment of moderate to severe acne. The composition of the drug product is provided below.

Table 3.2.P.1–1 Qualitative and quantitative composition of IDP-126 Gel

Component	Reference to Quality Standard	Function	Concentration (mg/g)	Concentration (b) (4)
Clindamycin phosphate	USP	Active	12.0	
Benzoyl peroxide, hydrous	USP	Active	(b) (4)	
Adapalene, micronized	USP	Active	1.5	
Propylene Glycol	USP	(b) (4)		
Carbomer homopolymer type C (Carbomer 980)	NF			
Potassium hydroxide	NF			
Purified water	USP			

[a] Equivalent to 1% clindamycin

(b) (4)

USP = United States Pharmacopeia

NF = National Formulary

Description of container closure system –

(*3.2.P.1 description-and-composition.pdf and 3.2.P.7 container-closure-system.pdf)*

A complete description of the container/closure system is provided in.P.7. Briefly, IDP-126 Gel is packaged in 20g and 50g (b) (4) bottles fitted with pumps and (b) (4) caps (*See Table 3.2.P.7–1*). A 3.5g (physician sample size) is also packaged in laminate tubes with (b) (4) caps (*See Table 3.2.P.7–2*).

Reviewer's Assessment: The drug product is a [redacted] (b) (4), multi-use, [redacted] (b) (4) gel formulation indicated for topical use. Based on the above information the reviewer has concluded that the applicant has provided adequate description of the drug product composition and the packaging system to support the manufacturing process for the drug product.

Acceptable

P.2 Pharmaceutical Development

(b) (4)

[redacted]

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/s/

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CHAPTER IV: LABELING

IQA NDA Assessment Guide Reference

1.0 PRESCRIBING INFORMATION

Assessment of Product Quality Related Aspects of the Prescribing Information:

The labeling and labels are not deemed ready for approval in its present form per 21 CFR 314.125 (b)(6) from the CMC labeling perspective until the deficiencies listed at the end of this review are satisfactorily resolved.

(b) (4)

[redacted]

Item	Information Provided in the NDA	Assessor's Comments
Product Title in Highlights		

Proprietary name	**CABTREO**	**Adequate**
Established name(s)	(b) (4)	**Adequate** - clindamycin phosphate has been used as established name in multiple approved drugs - Minor edits to change to read "(clindamycin phosphate, adapalene, and benzoyl peroxide)".
Route(s) of administration	(b) (4)	**Not Adequate** - Change to "topical gel"
Dosage Forms and Strengths Heading in Highlights		
Summary of the dosage form(s) and strength(s) in metric system.	(b) (4)	**Not Adequate** - Changes being made in the sharePoint to include package information as: "Topical gel: 1.2% clindamycin phosphate, 0.15% adapalene, and 3.1% benzoyl peroxide. CABTREO is supplied in 20-gram and 50-gram tubes and 20-gram and 50-gram pumps. (3)"
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored"	N/A	
For injectable drug products for parental administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use). Other package terms include pharmacy bulk package and imaging bulk package.	N/A	

1.2 FULL PRESCRIBING INFORMATION

1.2.1 Section 2 (DOSAGE AND ADMINISTRATION)

2 DOSAGE AND ADMINISTRATION

(b) (4)

Item	Information Provided in the NDA	Assessor's Comments
DOSAGE AND ADMINISTRATION section		
Special instructions for product preparation (e.g., reconstitution and resulting concentration, dilution, compatible diluents, storage conditions needed to maintain the stability of the reconstituted or diluted product)	- Apply a thin layer of CABTREO to the affected area once daily. - CABTREO is for topical use only. Not for oral, ophthalmic, or intravaginal use.	**Adequate**

1.2.2 Section 3 (DOSAGE FORMS AND STRENGTHS)

(b) (4)

Item	Information Provided in the NDA	Assessor's Comments
DOSAGE FORMS AND STRENGTHS section		
Available dosage form(s)	(b) (4)	**Adequate**
Strength(s) in metric system	(b) (4)	**Not Adequate** - Changes to the following in sharePoint as: "Topical gel: 1.2% clindamycin phosphate, 0.15% adapalene, and 3.1% benzoyl peroxide as a white to off-white, opaque gel. CABTREO is supplied in 20-gram and 50-gram tubes and 20-gram and 50-gram pumps."
If the active ingredient is a salt, apply the USP Salt Policy per FDA Guidance	(b) (4)	**Adequate**
A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, and imprinting	white to off-white, opaque, (b) (4) gel	**Adequate**
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored"	N/A	
For injectable drug products for parental administration, use appropriate labeling term (e.g., single-dose, multiple-dose, single-patient-use). Other package type terms include pharmacy bulk package and imaging bulk package.	N/A	

(b) (4)

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Item	Information Provided in the NDA	Assessor's Comments
DESCRIPTION section		
Proprietary and established name(s)	Proprietary name: CABTREO Established name: clindamycin phosphate, adapalene, benzoyl peroxide	**Adequate**
Dosage form(s) and route(s) of administration	(b) (4)	**Adequate**
If the active ingredient is a salt, apply the USP Salt Policy and include the equivalency statement per FDA Guidance.	12 mg (1.2%) clindamycin phosphate (equivalent to 10 mg (1%) clindamycin	**Adequate**
List names of all inactive ingredients. Use USP/NF names. Avoid Brand names.	Inactive ingredients: carbomer homopolymer type C (carbomer 980), potassium hydroxide, propylene glycol, and purified water	**Adequate**
For parenteral injectable dosage forms, include the name and quantities of all inactive ingredients. For ingredients added to adjust the pH or make isotonic, include the name and statement of effect.	N/A	
If alcohol is present, must provide the amount of alcohol in terms of percent volume of absolute alcohol	N/A	
Statement of being sterile (if applicable)	N/A	
Pharmacological/ therapeutic class	N/A	**Adequate** Clindamycin phosphate: antibiotic Adapalene: a naphthoic acid derivative with retinoid-like properties Benzoyl peroxide: (b) (4)
Chemical name, structural formula, molecular weight	Provided	**Adequate**
If radioactive, statement of important nuclear characteristics.	N/A	

Other important chemical or physical properties (such as pKa or pH)	- (b) (4) - -	**Adequate** - Rearranged description in the sharePoint as: "CABTREO (clindamycin phosphate, adapalene, and benzoyl peroxide) topical gel is a white to off-white, opaque gel. Each gram of CABTREO contains 12 mg (1.2%) clindamycin phosphate, equivalent to 10 mg (1%) clindamycin and 1.5 mg (0.15%) adapalene, and 31 mg (3.1%) benzoyl peroxide. Clindamycin phosphate is a water-soluble ester of the semisynthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent antibiotic lincomycin. Adapalene, a synthetic retinoid, is a naphthoic acid derivative with retinoid-like properties. Benzoyl peroxide is an oxidizing agent."
For oral prescription drug products, include gluten statement if applicable	N/A	
Remove statements that may be misleading or promotional (e.g., "synthesized and developed by Drug Company X," "structurally unique molecular entity"	N/A	

1.2.4 Section 16 (HOW SUPPLIED/STORAGE AND HANDLING)

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Item	Information Provided in the NDA	Assessor's Comments
HOW SUPPLIED/STORAGE AND HANDLING section		
Available dosage form(s)	(b) (4)	**Adequate**
Strength(s) in metric system	1.2%/0.15%/3.1%	**Adequate** - Editorial change made in sharePoint as" CABTREO (clindamycin phosphate, adapalene, and benzoyl peroxide) topical gel is a white to off-white, opaque gel. CABTREO contains 1.2% clindamycin phosphate, 0.15% adapalene, and 3.1% benzoyl peroxide and is supplied as follows…"
Available units (e.g., bottles of 100 tablets)	- 20 g tube (NDC 0187-0006-20) - 50 g tube (NDC 0187-0006-50) - 20 g pump (NDC 0187-0006-10) - 50 g pump (NDC 0187-0006-25)	**Adequate**
Identification of dosage forms, e.g., shape, color, coating, scoring, imprinting, NDC number	- white to off-white, opaque, - (b) (4) gel - NDC numbers provided	**Adequate**
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored"	N/A	
For injectable drug products for parental administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use). Other package terms include pharmacy bulk package and imaging bulk package.	N/A	
Special handling about the supplied product (e.g., protect from light, refrigerate). If there is a statement to "Dispense in original container," provide reason why (e.g. to protect from light or moisture, to maintain stability, etc.)	**Dispensing Instructions for the Pharmacist** - Dispense CABTREO with a 10-week expiration date. - Specify (b) (4)	**Adequate**
If the product contains a desiccant, ensure the size and shape differ from the dosage form and desiccant has a warning such as "Do not eat."	N/A	

Storage conditions. Where applicable, use USP storage range rather than storage at a single temperature.	**Storage and Handling** - (b) (4) - Keep away from heat. - Store pump upright. (b) (4)	**Adequate** - Deleted (b) (4) (b) (4) in the sharePoint
Latex: If product does not contain latex and manufacturing of product and container did not include use of natural rubber latex or synthetic derivatives of natural rubber latex, state: "Not made with natural rubber latex. Avoid statements such as "latex-free."	N/A	
Include information about child-resistant packaging	N/A	

1.2.5 Other Sections of Labeling

N/A

1.2.6 Manufacturing Information After Section 17 (for drug products)

Item	Information Provided in the NDA	Assessor's Comments
Manufacturing Information After Section 17		
Name and location of business (street address, city, state and zip code) of the manufacturer, distributor, and/or packer	Distributed by: Bausch Health US, LLC Bridgewater, NJ 08807 USA Manufactured by: Bausch Health Companies Inc. Laval, Quebec H7L 4A8, Canada	**Adequate**

2.0 PATIENT LABELING

The following CMC information provided in the Patient Information is adequate

Important information: CABTREO is for use on skin only (topical use). Do not use CABTREO in your eyes, mouth, or vagina.

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Item	Information Provided in the NDA	Assessor's Comments about Carton Labeling
Proprietary name, established name, and dosage form (font size and prominence	CABTREO (clindamycin phosphate, adapalene, and benzoyl peroxide) (b) (4)	**Not Adequate** - Change dosage form to "topical gel"
Dosage strength	1.2% /0.15%/3.1%	**Adequate**
Route of administration	For Topical Use Only Not for Oral, Ophthalmic, or Intravaginal Use	**Adequate**
If the active ingredient is a salt, include the equivalency statement per FDA Guidance	Each gram contains 12 mg (1.2%) clindamycin phosphate, equivalent to 10 mg (1%) clindamycin… On c/c labels for the commercial sizes but not for the patient sample	**Adequate** - It is acceptable not to show all the information on the label of patient sample due to constrained space (to be consistent with the approved drugs)
Net contents (e.g. tablet count)	20 g (50g and 3.5 g for the other sizes)	**Adequate**
"Rx only" displayed on the principal display	Provided	**Adequate**
NDC number	Provided	**Adequate**
Lot number and expiration date	Provided	**Adequate**
Storage conditions. If applicable, include a space on the carton labeling for the user to write the new BUD.	**On tubes and pumps:** Use by date handwritten on your label or within 10 weeks of dispensing date. Store at room temperature at or below 25°C (77°F). Do not freeze. Space for Use By date is available **On carton:** ATTENTION PHARMACIST: Prior to Dispensing: Store in a refrigerator, 2° to 8°C (36° to 46°F). Do not freeze. Dispensing Instructions: Dispense CABTREO™ (b) (4) with a 10-week expiration date. Store at room temperature up to 25°C (77°F). Do not freeze. Space for Use By date is available	**Adequate** - Consistent with the approved Onexton and Acanya
For injectable drug products for parental administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use)	N/A	
Other package terms include pharmacy bulk package and imaging bulk package which require "Not for direct infusion" statement.	N/A	

If alcohol is present, must provide the amount of alcohol in terms of percent volume of absolute alcohol	N/A	
Bar code	Provided	**Adequate**
Name of manufacturer/distributor	Provided	**Adequate**
Medication Guide (if applicable)	Recommended Dosage: See prescribing information.	**Adequate**
No text on Ferrule and Cap overseal	N/A	
When a drug product differs from the relevant USP standard of strength, quality, or purity, as determined by the application of the tests, procedures, and acceptance criteria set forth in the relevant compendium, its difference shall be plainly stated on its label.	N/A	
And others, if space is available	- Keep out of reach of children - Each gram contains: 12 mg (1.2%) clindamycin phosphate, equivalent to 10 mg (1%) clindamycin and 1.5 mg (0.15%) adapalene and 31 mg (3.1%) benzoyl peroxide in a base of carbomer homopolymer type C (carbomer 980), potassium hydroxide, propylene glycol, and puried water. - Precautions: (b) (4) Avoid contact with eyes and mucous membranes. May bleach colored fabric or hair.	**Adequate**

Assessment of Carton and Container Labeling: *Not Adequate*

- Change the dosage form from (b) (4) to "topical gel". (b) (4)

ITEMS FOR ADDITIONAL ASSESSMENT

List of Deficiencies

The following comments have been conveyed to the OND review team and to be conveyed to the applicant.

- The dosage form should be changed from (b) (4) to "topical gel" throughout the labeling and labels.
- Minor editorial changes listed in the above review sections were made in the PI in SharePoint.

Overall Assessment and Recommendation:

The labeling and labels are not deemed ready for approval in its present form per 21 CFR 314.125 (b)(6) from the CMC labeling perspective until the deficiencies listed above are satisfactorily resolved.

Primary Labeling Assessor Name and Date:

Zhengfang Ge, Ph. D.
Reviewer, BRANCH IV/DIVISION II
OFFICE OF NEW DRUG PRODUCT

Secondary Assessor Name and Date (and Secondary Summary, as needed):

Nina Ni, Ph. D.
Branch Chief, BRANCH IV/DIVISION II
OFFICE OF NEW DRUG PRODUCT

Zhengfang Ge

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Nina Ni

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