CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214518Orig1s000

PRODUCT QUALITY REVIEW(S)

FDA U.S. FOOD & DRUG ADMINISTRATION

RECOMMENDATION

☒ Approval
☐ Approval with Post-Marketing Commitment
☐ Complete Response

NDA 214518
Assessment #1

Drug Product Name	TPOXX (tecovirimat)
Dosage Form	Injection
Strength	200 mg/20 mL (10 mg/mL)
Route of Administration	Intravenous
Rx/OTC Dispensed	Rx
Applicant	SIGA Technologies, Inc.
US agent, if applicable	N/A

Submission(s) Assessed	Document Date	Discipline(s) Affected
SN 0001 Original NDA	4/30/2021	All: API, DP, OPMA, Micro
SN 0004	7/15/2021	DP
SN 0006	8/25/2021	DP
SN 0008	10/1/2021	DP, Micro
SN 0010	10/18/2021	DP
SN 0012	11/10/2021	OPMA
SN0014	11/24/2021	DP
SN 0016	12/22/2021	DP
SN 0019	02/16/2022	DP

QUALITY ASSESSMENT TEAM

Discipline	Primary Assessor	Secondary Assessor
Drug Substance	Katherine Windsor	Paresma Patel
Drug Product	Peter Guerrieri	David Claffey
Manufacturing	Ying Wang	Paresma Patel
Microbiology	Jennifer Sykora	Jesse Wells
Biopharmaceutics	NA	
Regulatory Business Process Manager	Shamika Brooks/Erica Keafer	
Application Technical Lead	Erika Englund/Xiao Hong Chen	

Laboratory (OTR)	NA	
Environmental	Peter Guerrieri	David Claffey

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)	V		(b) (4)	Adequate	5/5/2022	DMF was reviewed and found adequate.
	III			Adequate	3/30/2022	No review is necessary as adequate in NDA.
	III			Adequate	3/30/2022	No review is necessary as adequate in NDA.
	III			Adequate	3/30/2022	No review is necessary as adequate in NDA.
	III			Adequate	3/30/2022	No review is necessary as adequate in NDA.
	IV			Adequate	3/30/2022	No review is necessary as adequate in NDA.

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

Document	Application Number	Description
Submission and reviews	IND 69019	Tecovirimat was originally studied under the IND.
Submission and reviews	IND 111390	IND 111390 was opened later for the IV formulation of tecovirimat.
Submission and reviews	NDA 208627	Some of the supporting API CMC information is

		referenced to the approved NDA 208627.

2. CONSULTS: NA

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

EXECUTIVE SUMMARY

For more details about the items in this template, please see the Executive Summary chapter of the NDA IQA Guide

I. RECOMMENDATIONS AND CONCLUSION ON APPROVABILITY

Based on adequate CMC information submitted and acceptable cGMP status for all manufacturing and controls facilities for the NDA, OPQ product review team recommends Approval for the CMC perspective.

II. SUMMARY OF QUALITY ASSESSMENTS

A. Product Overview

Smallpox has been one of the most important human pathogens. Although vaccines are approved, they are not universally available as prophylaxis for the general population because of the risk of serious adverse events, particularly for the immunosuppressed. Therefore, other post-exposure treatment modalities, such as safe, effective small molecule drugs, are needed to respond to a smallpox or other orthopoxvirus emergency particularly for individuals already exposed, after which the vaccine may no longer be effective. Tecovirimat (International Nonproprietary Name (INN), also known as ST-246®, SIGA-246 or TPOXX® in the United States), a tricyclononene compound, is such drug that has been approved for the indication.

Proposed Indication(s) including Intended Patient Population	TPOXX is an inhibitor of the orthopoxvirus VP37 envelope wrapping protein and is indicated for the treatment of human smallpox disease in adults and pediatric patients.
Duration of Treatment	14 days
Maximum Daily Dose	1200 mg
Alternative Methods of Administration	NA

B. Quality Assessment Overview

This NDA is for the IV formulation of tecovirimat in a single strength of 200 mg/20 mL indicated for the treatment of Smallpox disease in adults and pediatric patients. Tecovirimat capsules (200 mg) are approved under NDA 208627. Tecovirimat was originally studied under IND 69019 and IND 111390 was opened later for the IV formulation of tecovirimat. For the IV formulation the proposed maximum daily dose is (b) (4) The product is to be withdrawn from the vial, and diluted with 2 parts of either 0.9% NaCl or 5% dextrose solution. In-use stability data was provided. The overfill is (b) (4)

The drug substance is [redacted] a white to off-white solid and exhibits low solubility. Some of the supporting drug substance information is provided by referencing to the approved NDA 208627. The drug substance described in NDA 208627 [redacted] the minor differences in the manufacturing process between the two NDAs are described in section 3.2.S.2.2.

The drug product is the IV formulation of tecovirimat and includes hydroxypropyl-beta-cyclodextrin (8,000 mg/vial) and water for injection. The product is compounded, [redacted] glass vials and stoppered. The long-term storage conditions for the drug product are between 2°C to 8°C and the shelf life of 24-month is granted. No comparability protocol was proposed in the NDA.

Drug Substance: Adequate

Tecovirimat is a tetracyclic acyl hydrazide compound developed under FDA's "Animal Rule" and included in the Strategic National Stockpile as a treatment for smallpox. [redacted] (see the Drug Product Review for further details).

The applicant cross-referenced much of the CMC information for tecovirimat drug substance to NDA 208627 (TPOXX (tecovirimat) capsules for oral use). NDA 208627 was approved on 13-JUL-2018 and several CMC post-marketing supplements have been subsequently approved.

Batch data for drug substance batches used to manufacture drug product registration and validation batches and the drug substance specification used for retest by the drug product manufacturer were provided and found adequate. Specified and unspecified impurities are controlled within ICH Q3A recommended qualification and identification thresholds, respectively. Mutagenic impurity [redacted] is controlled within the ICH M7 acceptable intake. The retest period for [redacted] tecovirimat monohydrate is [redacted] months when stored at [redacted]).

Drug Product: Adequate

The product, Tecovirimat Injection 200 mg/20 ml (10 mg/mL), is a sterile, colorless to pale yellow solution intended for IV administration following dilution in 0.9% saline or 5% dextrose solution. The proposed commercial package is a 30 mL glass vial with a [redacted] stopper sealed with an aluminum overseal with a plastic flip off cap.

The proposed shelf life is 24 months under refrigerated (2°C – 8°C) conditions. Stability results were provided for three registration/process

validation batches in 30 mL vials (18 months long-term for two batches and 12 months long-term for one batch and 6 months accelerated). The results support the proposed shelf life under refrigerated conditions.

Labeling: Adequate

The Prescribing Information (PI) includes information for both TPOXX (tecovirimat) injection 200 mg/20 mL, the subject of this NDA, and TPOXX capsules 200 mg, which were previously approved (NDA 208627). The labeling review covers only the information pertinent to TPOXX (tecovirimat) injection.

Manufacturing: Adequate

(b) (4)

The DS and DP manufacturing and DS/DP testing facilities were deemed adequate based on their current cGMP compliance and past inspectional history.

Biopharmaceutics: N/A

No Biopharmaceutics review is necessary for the NDA.

Microbiology (if applicable): Adequate

Microbiology review of container closure integrity test to ensure the drug product sterility during storage has found acceptable. Sterility assurance of the drug product manufacturing has been adequately demonstrated with the following information:

- Equipment used in the manufacture of the proposed drug product
- Environmental monitoring during production of the proposed drug product.

(b) (4)

- Microbiology related specifications for the control of the proposed drug product and validation for bacterial endotoxin and sterility testing

C. Risk Assessment

From Initial Risk Identification			Assessment		
Attribute/ CQA	**Factors that can impact the CQA**	**Initial Risk Ranking**	**Risk Mitigation Approach**	**Final Risk Evaluation**	**Lifecycle Considerations/ Comments**
Sterility	• Formulation • Container closure • Process parameters • Scale/equipments • Site	H	(b) (4)	Acceptable	
Endotoxin /pyrogen	• Formulation • Container closure • Process parameters • Scale/equipments • Site	M		Acceptable	
Assay, Stability	• Formulation • Container closure • Raw materials • Process parameters • Scale/equipments • Site	L		Acceptable	
Extractables and leachables	• Formulation • Container closure • Raw materials • Process parameters • Scale/equipments • Site	M		Acceptable	
Particulate	• Formulation • Container closure • Raw materials • Process parameters • Scale/equipments • Site	M		Acceptable	
pH	• Formulation • Container closure • Raw materials • Process parameters • Scale/equipments • Site	L		Acceptable	
In-use stability	• Formulation • Container closure • Raw materials • Process parameters • Scale/equipments • Site	L		Acceptable	

D. List of Deficiencies for Complete Response

1. Overall Quality Deficiencies *(Deficiencies that affect multiple sub-disciplines)*

None.

2. Drug Substance Deficiencies

None.

3. Drug Product Deficiencies

None.

4. Labeling Deficiencies

None.

5. Manufacturing Deficiencies

None.

6. Biopharmaceutics Deficiencies

None.

7. Microbiology Deficiencies

None.

8. Other Deficiencies *(Specify discipline, such as Environmental)*

None.

Application Technical Lead Name and Date:
Xiao Hong Chen April 19, 2022

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CHAPTER VII: MICROBIOLOGY

IQA NDA Assessment Guide Reference

Product Information	
NDA Number	214518
Assessment Cycle Number	01
Drug Product Name/ Strength	Tecovirimat Injection 10 mg/mL
Route of Administration	Intravenous
Applicant Name	SIGA Technologies, Inc., 4575 SW Research Way, Suite 110, Corvallis, OR 97333 USA
Therapeutic Classification/ OND Division	OID/DAV
Manufacturing Site	Patheon Manufacturing Services, LLC., 590 Martin Luther King Jr. Highway, Greenville, NC 27834 USA
Method of Sterilization	(b) (4)

Assessment Recommendation: **Adequate**

Assessment Summary:

List Submissions being assessed (table):

Document(s) Assessed	Date Received
Seq 0001	04/30/2021
Seq 0008	10/01/2021
Seq 0012	11/10/2021

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

Remarks: None

Concise Description of Outstanding Issues: None

Supporting Documents:

- **DMF (b) (4) for the overall drug product manufacturing information on (b) (4)**
- **Microbiology review (b) (4).docx (dated 5/5/2020; Adequate) for buildings and facilities information and environmental monitoring information (b) (4)**
- **Microbiology review (b) (4).pdf (dated 5/16/2018; Adequate) for information on the buildings and facilities used for DP manufacturing on (b) (4)**

- **Microbiology review [redacted].docx (dated 10/19/2021; Adequate) for revalidation studies for manufacturing and sterilization equipment used [redacted]**
- **DMF [redacted]**
- **Microbiology review [redacted].docx, dated 1/29/2020 (Adequate), for the most recent review [redacted]**

P.1 DESCRIPTION OF THE COMPOSITION OF THE DRUG PRODUCT

- **Description of drug product** (see 3.2.P.1 on page 1) – Tecovirimat Injection (10 mg/mL) is a sterile, colorless to pale yellow solution free of visible particles that is intended for IV use. The DP is manufactured as a single-use, 20 mL presentation. The DP is packaged in a 30 mL glass vial with a 20 mm, grey rubber stopper and aluminum seal.

- **Drug product composition** (see 3.2.P.1 on page 2) –

Ingredient	Function	Content per Vial
Tecovirimat	API	200 mg
Hydroxypropyl-B-cyclodextrin	[redacted]	8000 mg
Water for Injection		q.s. to 20 mL

Target overfill is [redacted]mL

- **Description of container closure system** (see 3.2.P.1 on page 3) –

Configuration	Component	ID Number	Description	Manufacturer
10 mg/mL vial	Vial	[redacted]		
	Rubber stopper			
	Seal			

Reviewer's Assessment: ***Adequate***

The applicant provided an adequate description of the drug product composition and the container closure system designed to maintain product sterility.

P.2 PHARMACEUTICAL DEVELOPMENT

P.2.5 MICROBIOLOGICAL ATTRIBUTES

Container/Closure and Package Integrity

(See Seq 0001 in 3.2.P.7 in "VAL-18392-CCIT Reportv-Patheon")

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CHAPTER IV: LABELING

For more details about the items in this template, please see Chapter IV (Labeling) of the NDA IQA Guide

1.0 PRESCRIBING INFORMATION

Assessment of Product Quality Related Aspects of the Prescribing Information:

The Prescribing Information (PI) includes information for both TPOXX (tecovirimat) injection 200 mg/20 mL, the subject of this NDA, and TPOXX capsules 200 mg, which were previously approved (NDA 208627). This review covers only the information pertinent to TPOXX (tecovirimat) injection.

1.1 HIGHLIGHTS OF PRESCRIBING INFORMATION

Item	Items in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
Product Title in Highlights		
Established name(s)[1]	Adequate	TPOXX (tecovirimat) injection
Route(s) of administration	Adequate	For intravenous use
Dosage Forms and Strengths Heading in Highlights		
Summary of the dosage form(s) and strength(s) in metric system	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.	Adequate	Single-dose
If the drug product contains an active ingredient that is a	N/A	

[1] Established name = [Drug] [Route of Administration] [Dosage Form]

salt, clearly state whether the strength is based on the active moiety (e.g., Tablets: 10 mg of drug-x) or active ingredient (e.g., Tablets: 10 mg of drug-x hydrochloride).		

1.2 FULL PRESCRIBING INFORMATION

1.2.1 Section 2 (DOSAGE AND ADMINISTRATION)

Item	Items in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
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)	Adequate	The solution is to be diluted in either 0.9% normal saline or 5% dextrose solution. Appropriate directions for dilution and in-use storage are provided.
Important administration instructions supported by product quality information (e.g., do not crush or chew extended-release tablets, instructions for mixing with food)	Adequate	See above.
For parenteral products: include statement: *"Parenteral drug products must be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit"*	Adequate	
If there is a USP monograph for the drug product and it contains a labeling requirement, ensure the labeling	N/A	

requirement is fulfilled. Note the labeling requirement may be applicable to another section of the PI (e.g., Section 11).		
For radioactive products, include radiation dosimetry for the patient and healthcare practitioner(s) who administer the drug	N/A	
For hazardous products, include the statement *"DRUG X is a hazardous drug. Follow applicable special handling and disposal procedures.*[x]*"* with x numerical citation to "OSHA Hazardous Drugs".	N/A	

1.2.2 Section 3 (DOSAGE FORMS AND STRENGTHS)

Item	Items in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
DOSAGE FORMS AND STRENGTHS section		
Available dosage form(s)	Adequate	Injection: 200 mg/20 mL (10 mg/mL) clear, colorless to pale yellow solution in a single-dose vial for further dilution
Strength(s) in metric system	Adequate	
If the active ingredient is a salt, apply the USP Salt Policy per FDA Guidance. Clearly state whether the strength is based on the active moiety (e.g., Tablets: 10 mg of drug-x) or active ingredient (Tablets: 10 mg of drug-x hydrochloride).	N/A	
A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, imprinting, and color and clarity of the solution, when applicable	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 type terms include pharmacy bulk package and imaging bulk package.	Adequate	

Section 11 (DESCRIPTION)

Item	Items in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
DESCRIPTION section		
Proprietary and established name(s)	Adequate	
Dosage form(s) and route(s) of administration	Adequate	
If the active ingredient is a salt, apply the USP Salt Policy and include the equivalency statement per Salt Guidance and MAPP. For example: "TRADENAME contains 100 mg of drug-x (equivalent to 123.7 mg of drug-x hydrochloride)"	N/A	
List names of all inactive ingredients. Use USP/NF names in alphabetical order. Avoid brand names.	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.	Adequate	
If alcohol is present, must provide the amount of alcohol in terms of percent volume of absolute alcohol	N/A	
Sterility statement (if applicable)	Adequate	
Pharmacological/Therapeutic class	Adequate	
Chemical name, structural formula, molecular weight	Adequate	
If radioactive, statement of important nuclear characteristics.	N/A	
Other important chemical or physical properties (such as pKa or pH)	Adequate	

Section 11 (DESCRIPTION) Continued

Item	Items in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
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	
If there is a USP monograph for the drug product and it contains a labeling requirement, ensure the labeling requirement is fulfilled. Note the labeling requirement may be applicable to another section of the PI (e.g., Section 2).	N/A	

1.2.4 Section 16 (HOW SUPPLIED/STORAGE AND HANDLING)

Item	Items in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
HOW SUPPLIED/STORAGE AND HANDLING section		
Available dosage form(s)	Adequate	
Strength(s) in metric system	Adequate	
Available units (e.g., bottles of 100 tablets)	Adequate	
Identification of dosage forms (e.g., shape, color, coating, scoring, imprinting, and color and clarity of the solution, when applicable); Include NDC(s)	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.	Adequate	
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.). For hazardous drugs, state "DRUG X is a hazardous drug. Follow applicable special handling and disposal procedures.[x]" with x numerical citation to "OSHA Hazardous Drugs."	Adequate	

Section 16 (HOW SUPPLIED/STORAGE AND HANDLING) (Continued)

Item	Items in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
Storage conditions. Where applicable, use USP storage range rather than storage at a single temperature.	Adequate	
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."*	Adequate	
Include information about child-resistant packaging	N/A	

1.2.5 Other Sections of Labeling

1.2.6 Manufacturing Information After Section 17 (for drug products)

Item	Items in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
Manufacturing Information After Section 17		
Name and location of business (street address, city, state, and zip code) of the manufacturer, distributor, and/or packer	Adequate	

2.0 PATIENT LABELING

Assessment of Product Quality Related Aspects of Patient Labeling (e.g., Medication Guides, Instructions for Use, Patient Information):

Item	Items in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments about Carton Labeling (If an item is Inadequate, provide more details on the issues, as appropriate)
Established name[2]	Adequate	
Special preparation instructions (if applicable)	Adequate	
Storage and handling information (if applicable)	Adequate	
If the product contains a desiccant, ensure the desiccant has a warning (e.g., "Do not eat.") and the size and shape of the desiccant differs from the dosage form.	N/A	
Active ingredient(s) (if applicable)	Adequate	
Alphabetical listing of inactive ingredients (if applicable)	Adequate	
Name and location of business (street address, city, state, and zip code) of manufacturer, distributor, and/or packer	Adequate	

Any deficiencies should be listed at the end in the "ITEMS FOR ADDITIONAL ASSESSMENT."

3.0 CONTAINER AND CARTON LABELING

3.1 Container Labels

(b) (4)

3.2 Carton Labeling

1 Page of Draft Labeling has been Withheld in Full as b4 (CCI/TS) immediately following this page

[2] Established name = [Drug] [Route of Administration] [Dosage Form]

Item	Items in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments about Carton Labeling (If an item is Inadequate, provide more details on the issues, as appropriate)
Established name[3], (font size and prominence)	Adequate	
Strength(s) in metric system	Adequate	
Route(s) of administration	Adequate	
If the active ingredient is a salt, include the equivalency statement per Salt Guidance and MAPP.	N/A	
Net contents (e.g., tablet count, volume of liquid)	Adequate	
"Rx only" displayed on the principal display	Adequate	
NDC	Adequate	
Lot number and expiration date	Adequate	SIGA requested an exception as outlined in paragraph (f) of 21 CFR §201.26, *Exceptions or Alternatives to Labeling Requirements for Human Drug Products Held by the SNS*, to the following labeling requirement: 21 CFR §201.17: *Drugs; location of expiration date*. This exception pertains to product to be stored in the SNS. DMEPA reviewed and deemed acceptable.
Storage conditions. If applicable, include a space on the carton labeling for the user to write the new beyond-use-date (BUD).	Adequate	
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, and these products require a "Not for direct infusion" statement.	Adequate	

[3] Established name = [Drug] [Route of Administration] [Dosage Form]

For parenteral injectable dosage forms, include the name and quantities of all active and inactive ingredients in alphabetical order. For ingredients added to adjust the pH or make isotonic, include the name and statement of effect.	Adequate	
If alcohol is present, must provide the amount of alcohol in terms of percent volume of absolute alcohol	N/A	
Linear Bar code	Adequate	

Item	**Items in Proposed Labeling** (choose "Adequate", "Inadequate", or "N/A")	**Assessor's Comments about Carton Labeling** (If an item is Inadequate, provide more details on the issues, as appropriate)
Name of manufacturer/distributor /packer	Adequate	
If there is a Medication Guide, must include a statement about dispensing a Medication Guide to each patient.	N/A	
No text on Ferrule and Cap overseal, unless a cautionary statement is required.	Adequate	
If there is a USP monograph for the drug product and it contains a labeling requirement, ensure the labeling requirement is fulfilled.	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.	N/A	

Assessment of Carton and Container Labeling: Adequate

ITEMS FOR ADDITIONAL ASSESSMENT

Requested edits to be conveyed to OND:

N/A

Overall Assessment and Recommendation:

Primary Labeling Assessor Name and Date: Pete Guerrieri, PhD

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

Peter Guerrieri

Digitally signed by Peter Guerrieri
Date: 3/30/2022 11:14:08AM
GUID: 54eb8ba100062ea99cbaab7c64143df3

David Claffey

Digitally signed by David Claffey
Date: 3/30/2022 06:12:20PM
GUID: 508da71e00029e20b201195abff380c2

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/s/

XIAOHONG CHEN
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