CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214187Orig1s000

OTHER REVIEW(S)

Division of Antivirals

REGULATORY PROJECT MANAGER LABELING REVIEW

Applications:

NDA 214187
NDA 208341/S-17

Name of Drug:

Epclusa (sofosbuvir and velpatasvir), tablets, 400 mg/100 mg and 200 mg/50 mg

Epclusa (sofosbuvir and velpatasvir), oral pellets, 200 mg/50 mg and 150 mg/37.5 mg

Applicant: Gilead Sciences, Inc.

Labeling Reviewed

Submission Dates: Prescribing Information (PI) (May 7, 2021)
Patient Package Insert (PPI) (May 17, 2021)
Instructions for Use (IFU), oral pellet only (May 17, 2021)

Background and Summary Description:

On December 15, 2020, Gilead Sciences, Inc., submitted original NDA 214187, for Epclusa (sofosbuvir and velpatasvir) oral pellets and an efficacy supplement, NDA 208341/S-17, for Epclusa (sofosbuvir and velpatasvir) tablets that proposed updating the labeling with dosing recommendations for the Epclusa pellets in patients 3 years and older. The submissions included data from study GS-US-342-1143, "A Phase 2, Open-Label, Multicenter, Multi-cohort Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir in Adolescents and Children with Chronic HCV Infection", cohort 3, which enrolled patients 3 to less than 6 years of age. In addition, the sponsor conducted a BE/BA study that showed the pellets are bioequivalent to the tablet formulation. The submissions were submitted to fulfill the requirements of the Written Request. In addition, the submissions were submitted to fulfill the following PREA PMR that was included in the June 28, 2016 Approval letter for NDA 208341/0:

3092-2 Conduct a study to evaluate the pharmacokinetics, safety and treatment response (using sustained virologic response) of sofosbuvir and velpatasvir in pediatric subjects 3 through less than 12 years of age with chronic hepatitis C virus infection.

Review

For the purposes of this review, the last approved PI and PPI (NDA 208341/S-15, approved on July 14, 2020) was compared to the draft PI received on May 7, 2021, and the draft PPI received on May 17, 2021.

GLOBAL EDITORIAL CHANGES

- Minor editorial and formatting revisions were made throughout the PI and PPI.
- Subsections were renumbered throughout the PI as an additional subsection was added to the label.
- Revised date will be updated to reflect Month and Year the action is taken in the PI and PPI.

HIGHLIGHTS OF PRESCRIBING INFORMATION

PRODUCT TITLE

- New dosage form was added

RECENT MAJOR CHANGES

The following sections were added under this heading

- Indications and Usage
- Dosage and Administration
    - Recommended Treatment Regimen and Duration in Patients 3 years of Age and Older (2.2).
    - Recommended Dosage in Pediatric Patients 3 Years of Age and Older (2.4)
    - Preparation and Administration of Oral Pellets (2.5).

INDICATIONS AND USAGE

- Expanded the patient population to include pediatric patients 3 years of age and removed the minimum patient weight requirement of 17 kg.

DOSAGE AND ADMINISTRATION

- Updated subsections 2.2, 2.3, and 2.4 with Epclusa oral pellets dosing information for patients 3 years of age and older and removed the minimum weight requirement of 17 kg.
- Added new subsection, 2.5 “Preparation and Administration of Oral Pellets”.

DOSAGE FORMS AND STRENGTHS

- Added information for Epclusa oral pellets: 200mg of sofosbuvir and 50 mg of velpatasvir; 150 mg of sofosbuvir and 37.5 mg of velpatasvir.

ADVERSE REACTIONS

- Adverse reactions updated to list the adverse reactions specific to the age group in which they were observed.

- Adverse reaction listed for adults and pediatric subjects 6 years of age and older as headache and fatigue
- The most common adverse reactions in pediatric subjects less than 6 years of age has been added and listed as vomiting and product use issue (spitting up the drug)

FULL PRESCRIBING INFORMATION: CONTENTS*

DOSAGE AND ADMINISTRATION

- Updated subsection 2.2 to remove the minimum weight limit for the patient and to update the minimum patient age to 3 years of age
- Updated subsection 2.4 to revise the minimum pediatric patient age from 6 to 3 years of age.
- Added subsection 2.5: Preparation and Administration of Oral Pellets

CLINICAL STUDIES

- Specified the subjects for the clinical trial summarized in subsection 14.5 were adults.

FULL PRESCRIBING INFORMATION (FPI)

1 INDICATIONS AND USAGE

- Revised the minimum patient age from 6 to 3 years of age.
- Removed the minimum patient body weight requirement.

2 DOSAGE AND ADMINISTRATION

- 2.2 Recommended Treatment Regimen and Duration in Patients 3 Years of Age and Older
  - Revised the minimum patient age from 6 to 3 years of age.
  - Removed the requirement of a minimum patient body weight.
  - Updated Table 1 to capture the above two revisions (e.g., age and body weight).

- 2.4 Recommended Dosage in Pediatric Patients 3 Years of Age and Older
  - Revised the minimum patient age from 6 to 3 years of age.
  - Removed the requirement of a minimum patient body weight.
  - Specified that in pediatric patients less than 6 years of age, to administer the oral pellets with food to increase the tolerability related to palatability.
  - Two columns added to Table 2 to
    - specify the EPCLUSA daily dose, and
    - list dosing via the oral pellet.
- Addition of subsection 2.5, entitled, “Preparation and Administration of Oral Pellets”.

3 DOSAGE FORMS AND STRENGTHS

- Added information for the Epclusa, oral pellets

6 ADVERSE REACTIONS

- 6.1 Clinical Trials Experience

- Adverse Reactions in Pediatric Subjects
  - Added adverse reaction data for pediatric subjects 3 to less than 6 years of age.

8 USE IN SPECIFIC POPULATIONS

- 8.4 Pediatric use
  - Updated with data from pediatric patients 3 years of age and older, with no minimum weight limit.

11 DESCRIPTION

- Added header for the description of Epclusa tablets.
- Added a new header and section describing the Epclusa pellet.

12 CLINICAL PHARMACOLOGY

- 12.3 Pharmacokinetics
  - Under Specific Populations: Pediatric Patients subsection, added the PK data from patients 3 to 6 years of age and older.
- 12.4 Microbiology
  - Under the Pediatric subsection, added data from patients 3 to less than 6 years of age.

14 CLINICAL STUDIES

- 14.1 Description of Clinical Trials
  - Updated Table 12 to include information from the trial (NCT03022981) in pediatric subjects 3 to less than 6 years of age.
  - Added a footnote to Table 12 to define treatment-experience (TE) subjects as those who have failed an interferon-based regimen with or without ribavirin and with or without an HCV protease inhibitor (boceprevir, simeprevir, or telaprevir).
- 14.7 Clinical Trials in Pediatric Subjects
  - Updated to include data from pediatric subjects 3 to less than 6 years of age.

16 HOW SUPPLIED/STORAGE AND HANDLING

- Added a header to identify the tablet specific information.
- Added a new section to provide for the supplied/storage and handling information for the new oral pellet formulation.

17 PATIENT COUNSELLING INFORMATION

- Added new text to refer the patient to the new Instructions for Use, which is a new component of the FDA-approved patient labeling.

PATIENT INFORMATION

- Updated header to add the oral pellets.
- Under the description, "What is EPCLUSA", updated to provide for information regarding the oral pellet.
  - The minimum patient age has been revised from 6 years to 3 years of age.

    - The lower weight limit of 17kg has been removed.
    - Added a statement to note that Epclusa contains both sofosbuvir and velpatasvir.
- Under the description, "How should I take EPCLUSA," updated to provide information regarding the oral pellet and revised patient population,
    - Added oral pellet as a formulation that can be taken by mouth.
    - The minimum patient age has been revised from 6 to 3 years of age.
    - An additional statement advising the patient to tell their healthcare provider if their child has problems with swallowing tablets.
    - Added reference to the new section to, "How should I give EPCLUSA oral pellets to my child?"
- Added a new section to provide information on how the EPCLUSA oral pellets should be given to a child.
- Updated the Possible Side Effects section to include the new data in children 3 to less than 6 years of age.
    - The already listed side effects are specified to be for adults and children 6 years an older.
    - Added the side effects for children younger than 6 years of age.
- Storage of EPCLUSA has been updated to list the storage information for Oral Pellets
    - The oral pellets are stored in cartons and packets, and directions have been added to not use EPCLUSA if the carton-tamper evident seal or the packet has been opened or damaged.
- Added the ingredients for the Oral Pellet.

Recommendations

The changes as proposed in the original NDA 214187 and supplemental NDA 208341/S-17 for Epclusa are acceptable and an approval letter will be sent. Please refer to the CDTL, division director, clinical, clinical pharmacology, clinical virology, CMC, DMEPA, OPDP, DMPP reviews for further information.

Talia Lindheimer, 06/03/2021

Regulatory Project Manager Date

Karen Winestock, 6/3/2021

Chief, Project Management Staff Date

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Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy

PATIENT LABELING REVIEW

Date:	May 11, 2021
To:	Talia Lindheimer Regulatory Project Manager Division of Antivirals (DAV)
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Morgan Walker, PharmD, MBA, CPH Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Nima Ossareh, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI) and Instructions for Use (IFU)
Drug Name (established name):	EPCLUSA (sofosbuvir and velpastavir)
Dosage Form and Route, Application Type/Number, Supplement Number:	tablets, for oral use, NDA 208341/S-017 oral pellets, for oral use, NDA 214187
Applicant:	Gilead Sciences, Inc.

1 INTRODUCTION

On December 14, 2020, Gilead Sciences, Inc. submitted for the Agency's review an original New Drug Application (NDA) 214187 for EPCLUSA (sofosbuvir and velpatasvir) oral pellets. The Applicant also submitted a Prior Approval Supplement (PAS) to their NDA 208341/S-017 for EPCLUSA (sofosbuvir and velpatasvir) tablets. The purpose of the original NDA and PAS is in support of proposed labeling changes to the Prescribing Information (PI) to include a new formulation, oral pellets, for use in the treatment of hepatitis C virus (HCV) infection in pediatric patients. Both NDAs will share the same PI and Patient Package Insert.

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a request by the Division of Antivirals (DAV) on December 18, 2020 for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) and Instructions for Use (IFU) for EPCLUSA (sofosbuvir and velpastavir) tablets and EPCLUSA (sofosbuvir and velpastavir) oral pellets.

DMPP conferred with the Division of Medication Error, Prevention, and Analysis (DMEPA) and a separate DMEPA review of the IFU will be forthcoming.

2 MATERIAL REVIEWED

- Draft EPCLUSA (sofosbuvir and velpastavir) tablets and EPCLUSA (sofosbuvir and velpastavir) oral pellets PPI and IFU received on December 14, 2020, and received by DMPP and OPDP on April 28, 2021.
- Draft EPCLUSA (sofosbuvir and velpastavir) tablets and EPCLUSA (sofosbuvir and velpastavir) oral pellets PI received on December 14, 2020, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on April 28, 2021.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss.

In our collaborative review of the PPI and IFU we:

- simplified wording and clarified concepts where possible
- ensured that the PPI and IFU are consistent with the Prescribing Information (PI)

- removed unnecessary or redundant information
- ensured that the PPI and IFU are free of promotional language or suggested revisions to ensure that it is free of promotional language
- ensured that the PPI and IFU meet the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)

4 CONCLUSIONS

The PPI and IFU are acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DMPP and OPDP on the correspondence.
- Our collaborative review of the PPI and IFU is appended to this memorandum. Consult DMPP and OPDP regarding any additional revisions made to the PI to determine if corresponding revisions need to be made to the PPI and IFU.

Please let us know if you have any questions.

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FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: 5/10/2021

To: Talia Lindheimer
Regulatory Project Manager
Division of Regulatory Operations for Infectious Disease

From: Nima Ossareh, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Sam Skariah, Team Leader, OPDP

Subject: OPDP Labeling Comments for EPCLUSA (sofosbuvir and velpatasvir) tablets, for oral use; EPCLUSA® (sofosbuvir and velpatasvir) oral pellets

NDA: 208341/S-17; 214187

In response to DAVP consult request dated December 18, 2020, OPDP has reviewed the proposed product labeling (PI) and patient package insert (PPI) for EPCLUSA (sofosbuvir and velpatasvir) tablets, for oral use and EPCLUSA® (sofosbuvir and velpatasvir) oral pellets.

PI: OPDP's comments on the proposed labeling are based on the draft PI and PPI received by electronic mail from Division of Antiviral Products (DAVP) on April 28, 2021 and are provided below.

PPI, IFU: A combined OPDP and Division of Medical Policy Programs (DMPP) review of the PPI will be completed under a separate cover.

Thank you for your consult. If you have any questions, please contact Nima Ossareh at (240) 402-2769 or nima.ossareh@fda.hhs.gov.

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MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING
Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

Date of This Memorandum:	April 14, 2021
Requesting Office or Division:	Division of Antivirals (DAV)
Application Type and Number:	NDA 214187 NDA 208341/S-17
Product Name and Strength:	Epclusa (sofosbuvir and velpatasvir) oral pellets, 150 mg/37.5 mg and 200 mg/50 mg Epclusa (sofosbuvir and velpatasvir) tablets, 200 mg/50 mg and 400 mg/100 mg
Applicant/Sponsor Name:	Gilead Science
OSE RCM #:	2020-2642-1
DMEPA Safety Evaluator:	Melina Fanari, RPh
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

1 PURPOSE OF MEMORANDUM

The Applicant submitted revised container labels and carton labeling received on April 7, 2021 for Epclusa. The Division of Antivirals (DAV) requested that we review the revised Instruction for Use (IFU), container labels and carton labeling for Epclusa (Appendix A) to determine if it is acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 CONCLUSION

The Applicant implemented all of our recommendations and we have no additional recommendations at this time.

[a] Fanari, Melina Label and Labeling Review for Epclusa (NDA 214187 and NDA 208341/S-17), Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Mar 26. RCM No.: 2020-2642.

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SEVAN H KOLEJIAN
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LABEL AND LABELING REVIEW
Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	March 26, 2021
Requesting Office or Division:	Division of Antivirals (DAV)
Application Type and Number:	NDA 214187 NDA 208341/S-17
Product Name and Strength:	Epclusa (sofosbuvir and velpatasvir) oral pellets, 150 mg/37.5 mg and 200 mg/50 mg Epclusa (sofosbuvir and velpatasvir) tablets, 200 mg/50 mg and 400 mg/100 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Gilead Science
FDA Received Date:	December 15, 2020
OSE RCM #:	2020-2642
DMEPA Safety Evaluator:	Melina Fanari, RPh
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

1 REASON FOR REVIEW

As part of the approval process for Epclusa (sofosbuvir and velpatasvir) oral pellets (NDA 214187) and 208341/S-17, the Division of Antivirals (DAV) requested that we review the proposed Epclusa prescribing information (PI), patient prescribing information (PPI), instruction for use (IFU), container labels, and carton labeling for areas of vulnerability that may lead to medication errors.

2 BACKGROUND

Epclusa tablet was approved June 28, 2016 (NDA 208341). Gilead has submitted a new NDA (214187) for an oral pellet formulation in addition to an efficacy supplement (NDA 208341/S-17) to revise the minimum patient age in labeling from 6 years to 3 years.

3 MATERIALS REVIEWED

Table 1. Materials Considered for this Label and Labeling Review

Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B
ISMP Newsletters*	C-N/A
FDA Adverse Event Reporting System (FAERS)*	D-N/A
Other	E-N/A
Labels and Labeling	F

N/A=not applicable for this review

*We do not typically search FAERS or ISMP Newsletters for our label and labeling reviews unless we are aware of medication errors through our routine postmarket safety surveillance

4 FINDINGS AND RECOMMENDATIONS

Tables 2 and 3 below include the identified medication error issues with the submitted prescribing information (PI), patient prescribing information (PPI), instruction for use (IFU), container labels, and carton labeling, our rationale for concern, and the proposed recommendation to minimize the risk for medication error. DMEPA will collaborate with DAV to provide edits related to below recommendations to sharepoint.

Table 2. Identified Issues and Recommendations for Division of Antivirals (DAV)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Full Prescribing Information – Section 2 Dosage and Administration			
1.	Table 2 combines recommended doses of both formulations and available strengths within one column.	Dosing recommendations are confusing and could lead to wrong dose medication errors.	Revise table 2 to include a separate column for the recommended dosages of each weight band for each formulation (tablet and oral pellets)
2.	Administration method without food is not stated.	Administration options are incomplete and could lead to confusion.	Add the following sentence as the 2nd sentence in the 2nd paragraph of section 2.5: "EPCLUSA oral pellets can be taken right in the mouth or with food. See Instructions for use"
Patient Package Insert (PPI)			
1.	'Do not chew warning is missing" under the '(b) (4) ' section.	Avoid chewing of pellets during patient administration.	Add the below statement as bullet #2 under the section entitled: (b) (4) ': "Pellets should be swallowed whole. Do not chew pellets."

Table 3. Identified Issues and Recommendations for Gilead Science (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Container Label(s)			
1.	Container labels for oral pellets Epclusa 150 mg/37.5 mg per packet and Epclusa 200 mg/50	Mitigate risk of wrong strength medication errors.	Revise the color scheme of the available packets so that each strength appears well differentiated.

Table 3. Identified Issues and Recommendations for Gilead Science (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
	mg per packet looks similar.		
Container label(s) and Carton Labeling			
2.	Active ingredient presentation incorporates a '/'.	Improve clarity.	Revise the presentation of the active ingredients to read as follows: 'Sofosbuvir and Velpatasvir' We note this is consistent with the currently marketed tablet formulation labels and labeling.
3.	Warning to not chew pellets missing.	Avoid chewing of pellets during patient administration.	Add the following statement to the principle display panel: 'Pellets should be swallowed whole. Do not chew pellets.'
Instruction for Use (IFU)			
1.	Figures G, H, I, J and K are repeated.	Remove redundancy and streamline IFU presentation.	Consider streamlining IFU to include the 1st step to Gather Supplies and 2nd step to Prepare and Administer a Dose which would include figures A-E followed by the 2 available options to administer Epclusa oral pellets (with food or pouring contents in mouth).
2.	Do not chew warning is missing under the important information section.	Avoid chewing of pellets during patient administration.	Add the below statement as bullet #2 under the section entitled: 'Important Information You need to Know Before taking Epclusa oral Pellets': "Pellets should be swallowed whole. Do not chew pellets."

5 CONCLUSION

Our evaluation of the proposed Epclusa prescribing information (PI), patient prescribing information (PPI), instruction for use (IFU), container labels, and carton labeling identified areas of vulnerability that may lead to medication errors. Above, we have provided recommendations in Table 2 for the Division and Table 3 for the Applicant. We ask that the Division convey Table 3 in its entirety to Gilead Science so that recommendations are implemented prior to approval.

APPENDICES: METHODS & RESULTS FOR EACH MATERIAL REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 4 presents relevant product information for Epclusa that Gilead Science submitted on December 15, 2020.

Table 4. Relevant Product Information for Epclusa

	Epclusa Pellets	Epclusa tablet
Initial Approval Date	N/A	June 28, 2016
Active Ingredient	sofosbuvir and velpatasvir	
Indication	EPCLUSA is indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection.	EPCLUSA is indicated for the treatment of adults and pediatric patients 6 years of age and older or weighing at least 17 kg with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection.
Route of Administration	Oral	
Dosage Form	Oral pellets	Oral tablets
Strength	150 mg/37.5 mg and 200 mg/50 mg	200 mg/50 mg and 400 mg/100 mg
Dose and Frequency	**Recommended Dosage in Pediatric Patients 3 Years and Older** Less than 17 kg- One 150 mg/37.5 mg packet of pellets once daily 17 kg to less than 30 kg- One 200 mg/50 mg tablet or one 200 mg/50 mg packet of pellets once daily. At least 30 kg- One 400 mg/100 mg tablet (or two 200 mg/50 mg tablets or two 200 mg/50 mg packets of pellets) once daily	**Recommended Dosage in Adult and Pediatric Patients 6 Years and Older or Weighing at Least 17 kg** 17 kg to less than 30 kg- One 200 mg/50 mg tablet once daily 30 kg and up- One 400 mg/100 mg tablet (or two 200 mg/50 mg tablets) once daily
(How Supplied	Cartons of 28 packets	Bottles of 28 tablets
Storage	Store below 30°C (86°F)	

APPENDIX B. PREVIOUS DMEPA REVIEWS

On March 5, 2021, we searched for previous DMEPA reviews relevant to this current review using the terms, Epclusa. Our search identified no relevant reviews related to these submissions.

APPENDIX F. LABELS AND LABELING

F.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[a] along with postmarket medication error data, we reviewed the following Epclusa labels and labeling submitted by Gilead Science.

- Container label(s) received on December 15, 2020
- Carton labeling received on December 15, 2020
- Instructions for Use, Patient Prescribing Information and Prescribing Information (Images not shown) received on \\CDSESUB1\evsprod\NDA214187\0001\m1\us\114-labeling\draft\labeling

F.2 Label and Labeling Images

Container label(s)

(b) (4)

[a] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

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

DATE: 2/18/2021

TO: Division of Antivirals (DAV)
Office of Infectious Diseases (OID)

FROM: Division of New Drug Study Integrity (DNDSI)
Office of Study Integrity and Surveillance (OSIS)

SUBJECT: **Decline to conduct an on-site inspection**

RE: NDA 214187

The Division of New Drug Study Integrity (DNDSI) within the Office of Study Integrity and Surveillance (OSIS) determined that inspections are not warranted at this time for the site listed below. The rationale for this decision is noted below.

Rationale

OSIS inspected the site in (b) (4), which falls within the surveillance interval. The inspection was conducted under the following submissions: (b) (4), and (b) (4) and (b) (4).

The final classification for the inspection was No Action Indicated (NAI).

Therefore, based on the rationale provided above, an inspection is not warranted at this time.

Inspection Site

Facility Type	Facility Name	Facility Address
		(b) (4)

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