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RESEARCH**

APPLICATION NUMBER:

215499Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	September 22, 2021
Application Type and Number:	NDA 215499
Product Name and Strength:	Apretude (cabotegravir extended-release injectable suspension), 600 mg/3 mL (200 mg/mL)
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	ViiV Healthcare Company (ViiV)
PNR ID #:	NDA 215499
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA 1 Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS
OMEPRM Deputy Director:	Lubna Merchant, MS, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Apretude, which was found conditionally acceptable under IND 109678 on April 16, 2021.^a Thus, ViiV submitted the name, Apretude, under NDA 215499 for review on July 23, 2021. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Apretude would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Antivirals (DAV) concurred with the findings of OPDP's assessment for Apretude.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The September 9, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Apretude.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Antivirals (DAV). At that time, we also requested additional information or concerns that could inform our review. On September 22, 2021, the Division of Antivirals (DAV) stated no additional concerns with the proposed proprietary name, Apretude.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Apretude, is acceptable.

If you have any questions or need clarifications, please contact Phuong B. Nguyen, OSE Project Manager, at 240-402-5827.

3.1 COMMENTS TO ViiV HEALTHCARE COMPANY

We have completed our review of the proposed proprietary name, Apretude, and have concluded that this name is acceptable.

^a Holmes, L. Proprietary Name Review for Apretude (IND 109678). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Apr 16. PNR ID No. 2020-1043518311.

If any of the proposed product characteristics as stated in your submission, received on July 23, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

APPEARS THIS WAY ON ORIGINAL

4 REFERENCE

- 1. *USAN Stems*** (<https://www.ama-assn.org/about/united-states-adopted-names-approved-stems>)

USAN Stems List contains all the recognized USAN stems.

APPEARS THIS WAY ON ORIGINAL

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/

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Signed on behalf of Lubna Merchant