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APPLICATION NUMBER:

210192Orig1s000

MICROBIOLOGY/VIROLOGY REVIEW(S)

DIVISION OF ANTIVIRAL PRODUCTS (HFD-530)
VIROLOGY REVIEW
NDA: 210192 SDN: 000 DATE REVIEWED: 09/14/2017
Virology Reviewer: Lisa K. Naeger, Ph.D.

NDA#: 210192 **Serial #:** 000
Reviewer's Name(s): Lisa K. Naeger, Ph.D.

Sponsor's Name and Address:
ViiV Healthcare Company
5 Moore Drive
Research Triangle Park, NC 27709

Initial Submission Dates:
Correspondence Date: 06/01/2017
CDER Receipt Date: 06/01/2017
Assigned Date: 06/01/2017
Review Complete Date: 11/08/2017
PDUFA Date: 11/17/2017

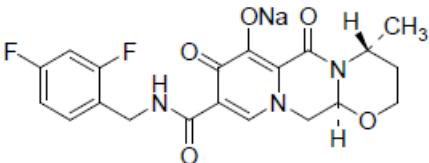
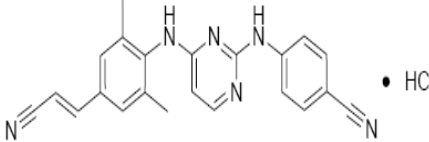
Amendments:

SDN	Date Submitted	Date Received	Date Assigned
003	06/13/2017	06/13/2017	07/05/2017
004	06/30/2017	06/30/2017	07/05/2017

Related/Supporting Documents: IND123306, RPV: IND67699; NDA-202022; DTG: IND75382; NDA-204790

Product Name(s)
Proprietary: JULUCA
Non-Proprietary/USAN: dolutegravir/rilpivirine

Product Names : Fixed dose combination of dolutegravir/rilpivirine

Product Name	Dolutegravir, DTG, TIVICAY®	Rilpivirine HCl, RPV, TMC278 EDURANT®
Chemical Structure		
Chemical Name	Sodium (4R,9aS)-5-Hydroxy-4-methyl-6,10-dioxo-3,4,6,9,9a,10-hexahydro-2H-1-oxa-4a,8a-diaza-anthracene-7-carboxylic acid 2,4-difluoro-benzylamide	4-[[4-[[4-[(1E)-2-cyanoethenyl]-2,6-dimethylphenyl]amino]-2-pyrimidinyl]amino] benzonitrile monohydrochloride
Molecular formula:	C ₂₀ H ₁₈ F ₂ N ₃ NaO ₅	C ₂₂ H ₁₉ N ₆ Cl
Molecular weight	441.36	402.88

Drug category: Antiviral
Indication: HIV-1 infection
Dosage Form/Route of administration: fixed-dose tablet/oral

The Clinical Virology Review is complete, and has been added to the NDA-210192 Multidisciplinary Review and Evaluation. My recommendation for this application is approval.

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/s/

LISA K NAEGER
10/25/2017

JULIAN J O REAR
10/26/2017