F. No. ND/MA/20/000068
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan,
Kotla Road, New Delhi
Dated: 29/7/2020

To
M/s Cipla Ltd.,
Cipla House, Peninsula Business Park,
Ganpatrao Kadam Marg, Lower Parel,
Mumbai, Maharastra, India – 400013.

Subject: Grant of permission to manufacture and market Remdesivir for Injection 100 mg/ vial (lyophilized) at the site M/s Cipla Ltd., M-61, M-62 & M-63, Verna Industrial Estate, Verna, Salcette, Goa-403722 - regarding

Reference: Your application no. ND/CT21/FF/2020/19823 dated 21.05.2020

Sir,

Please refer to the permission no.: MF-ND-109/2020 dated 20.06.2020 for manufacture and market Remdesivir for Injection 100 mg/ vial (lyophilized) granted by this office in Form CT-23 under Drugs & Cosmetics Act, 1940 and Rules there under and New Drugs and Clinical Trials Rules, 2019 there under, based on evaluation in consultation with Subject Expert Committee (SEC) as part of accelerated approval process considering the emergency situation and unmet medical need in light of Covid 19 outbreak for restricted emergency use in the country.

This office has no objection for your manufacturing and marketing of Remdesivir for Injection 100 mg/ vial (lyophilized) at additional site M/s Cipla Ltd., M-61, M-62 & M-63, Verna Industrial Estate, Verna, Salcette, Goa-403722 subject to the same conditions and restrictions as stipulated in the permission no.: MF-ND-109/2020 dated 20.06.2020.

Yours faithfully,

V.G.

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy to: -
1. The DDC(I), Central Drugs Standards Control Organisation, West Zone, 4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai – 400 008.
2. Director, Food and Drug Administration, Old IPHB Complex, Altinho, panaji, Goa-403001.