Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 195th meeting held on 01.12.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	F.NO. IND/CT/20/000037 2-Deoxy-D-Glucose oral powder	M/s Dr. Reddy	The firm presented the results of Phase III clinical trial before the committee. The committee noted the results of Phase III clinical Trial. After detailed deliberation, the committee recommended that the firm should present the detailed data specifically with respect to efficacy parameter for further review by the committee.
GCT Division			
2.	CT/119/21 (28255) LTX-109 3% Hydrogel	M/s. Parexel	The firm presented the proposed phase II study protocol no. C21-109-09, Version:3.1 dated 09-SEP-2021 with investigational product (IP) LTX-109 3% gel before the Committee. **Risk Vs Benefit:** The safety profile of the drug (IP-LTX-109) from the preclinical & clinical studies with topical administration justify the conduct of trial. **Innovations Vs existing therapeutic option:** As on date there is no approved treatment for the COVID-19. Hence, it has been proposed, as therapeutic (and later, potentially also targeted prophylactic) use of LTX-109 will most likely reduce overall transmissibility in the society and reduced progression to severe disease for individual patients infected with SARS-CoV-2 **Unmet Medical Need:** As on date there is no approved treatment for the COVID-19. Hence, it has been proposed, as therapeutic (and later, potentially also targeted prophylactic) use of LTX-109 will most likely reduce overall transmissibility in the society and reduced progression to severe disease for individual patients infected with SARS-CoV-2**.** The proposed trial, aim to evaluate the use of LTX-109 nasal gel for treatment of COVID-19 infection by application to the nasal cavity. The IP proposed as Prophylactic agent to reduce infection in exposed and vulnerable groups. After detailed deliberation, the Committee recommended for grant of permission to conduct the proposed study with the following conditions: **1)** The mild COVID patients should only be

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			included as per the Govt. of India/ICMR guidelines. **2)** Only RTPCR confirmed subjects within 72 hrs should be enrolled in the study. **3)** At screening, Serum pregnancy test should be performed instead of Urine pregnancy test with the women of child bearing potential (WOCBP). **4)** Standard operating procedure for rescue management under the proposed study should be prepared and submitted to CDSCO.
3.	CT/15/21 ATR-002	M/s. Clinexel Life Sciences	The firm presented the proposal for increase of number of subjects from 40 subjects to 80 subjects from India before the Committee. After detailed deliberation, the Committee noted that the applicant has not enrolled the 40 subjects as approved initially. Hence, the Committee did not recommend the increase in the no. of subjects as proposed.
4.	CT/133/20 EDP1815	M/s. Spectra Hospital Services	The firm presented the proposed protocol TACTIC-E, Amendment Version: 3.0 dated 09JUL2021 before the Committee. The Committee noted that now the applicant proposed to add new arm with inhaled Niclosamide (UNI911), which is not approved by any Health Authority. After detailed deliberation, the Committee recommended for approval of the proposed amendment with the following conditions: 1) The firm should submit the approval of the proposed protocol amendment from the other participating countries to CDSCO. 2) At screening, Serum pregnancy test should be performed instead of Urine pregnancy test with the women of child bearing potential (WOCBP) in India.