Recommendations of SEC (Pulmonary) made in its 55th meeting held on 09.11.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDCDivision			
1.	FDC/MA/21/000240 Fluticasone Furoate +Vilanterol Trifenatate eq. to Vilanterol (100mcg/200mcg+25 mcg) Dry Powder for inhalation	M/s. Glenmark Pharmaceuticals Ltd. India	The firm presented their proposal before the committee along with their proposal to conduct BA studies. The committee noted that the proposed FDC is already approved in EU and US. After detailed deliberation, the committee recommended for grant of permission for conducting the two proposed BA studies with the condition that the firm should present the results of the first BA study before initiating the second study for further consideration by the committee.
GCT Division			
2.	CT/105/21OnlineSubmission(27669) Rilematovir	M/s. J&J	The applicant presented the Phase II clinical trial protocol before the committee. **Assessment of risk vs. benefit to the patients:** The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity study, Phase I & II clinical study data justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic option:** The Purpose of the study is to evaluate efficacy of Rilematovir compared to placebo with respect to the time to resolution of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) symptoms. **Unmet Medical need in the country**: The test drug may potentially provide treatment in Adult Out patients with Respiratory Syncytial Virus (RSV) Infection who are at High Risk for RSV-related Disease Progression. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study with following conditions. 1) The firm should include atleast 50 % government sites. 2) Microbiologist should be Co-

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			Investigator/Sub-Investigator at every site in the proposed study.
3.	CT/108/21OnlineSubmission(27633) CSJ117	M/s. Novartis	The applicant presented the Phase II clinical trial protocol before the committee. **Assessment of risk versus benefit to the patient:** The safety profile of the drug from pre-clinical toxicological studies and clinical phase I study, may justify the conduct of the study. **Innovation vis –a- vis exiting therapeutic:** The primary objective of this study is to assess the effect of CSJ117 on disease/symptom burden after 12 weeks of treatment in patients with COPD. **Unmet Medical need in the country:** The test drug may be an alternative treatment option for subjects with COPD. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study with following conditions: 1) The firm should include atleast 50 % Government Sites. 2) The firm should define inclusion criteria for COPD patients with co-morbidities in Clinical Study Protocol rather than on the basis of Principal Investigator's discretion.
Medical Device Division			
4.	CI/MD/2021/43468 Thermal vapor lung treatment system generator (InterVapor Generator)	M/s. Aditya Pharma	The firm presented their proposal for conduct of post marketing clinical investigation before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV post market clinical investigation of the device in India subject to the condition that the firm should submit interim report after 36 months from the initiation of trial for review.