Recommendations of the SEC meeting to examine (COVID-19) related proposal under accelerated approval process made in its 248th meeting held on 26.05.2023 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000081 Umifenovir 400 mg tablets	M/s Medizest Pharmaceutical Private Limited	The firm presented the proposal for manufacturing and marketing of Umifenovir 400 mg tablets along with the results of Phase III clinical trial before the committee for restricted use under emergency situation in the country. The committee noted that the Umifenovir tablets is approved in countries like China & Russia for prophylaxis and treatment of influenza. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Umifenovir 400 mg tablets for restricted use under emergency situation in the country as add-on therapy for treatment of mild Covid-19 patients subject to the following condition:- 1. The product should be sold by retail under the prescription of medical specialists only. 2. The firm should conduct active PMS study in the country for which protocol should be submitted to CDSCO within three months from the date of approval of the drug for further review by the committee. 3. The firm should submit the package insert and fact sheet of the product.
GCT Division			
2.	CT/38/22 AKS-452	M/s Veeda	In light of earlier SEC recommendation dated 07/02/2023, the applicant presented revised protocol no 22-VIN-0076 version no-05date 07-04-2023 with increase no of

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
			sample size i.e. 3450 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm subject to the condition that more clinical trial sites should be added across the country.