Recommendations of the COVID-19 SEC made in its 99th meeting held on 05.08.2020 under accelerated approval process at CDSCO - HQ, New Delhi

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
FDC Division			
1.	FDC/MA/20/000103 Daclatasvir dihydrochloride IP equivalent to Daclatasavir 60 mg+ Sofosbuvir 400 mg Film coated tablet	M/s Mylan	Firm presented their proposal before the committee requesting for clinical trial waiver. The firm presented few Iranian studies conducted with the FDC on moderate to severe patients. Committee noted that this FDC is not approved anywhere in the world for use against Novel Corona virus SARS-COV-2. After detailed deliberation, committee recommended that firm should conduct a Phase-III clinical trial on Indian patients and accordingly Phase-III clinical trial protocol should be submitted for review by the committee.
2.	FDC/MA/000102 DDAC 10.14 %W/w + ADBAC 6.76W/W Surface disinfectant	M/s Alliance	Firm presented their proposal before the committee. The committee noted that this FDC is already approved by CDSCO in consultation with the SEC and now the firm has applied for additional indication for use against Novel Corona virus SARS-Cov-2. Committee also noted that this FDC is already approved by EPA of USA for use against Novel Corona virus SARS-Cov-2. After detailed deliberation committee recommended for grant of permission for manufacturing and marketing the product for the proposed additional indication.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
3.	FDC/MA/20/000104 ODDAC 6.510 %w/w+ DODAC 2.604% w/w+3.906%w/w +DDAC 3.906% w/w +ADBAC 8.680% w/w 21.7000%w/w	M/s Alliance	Firm presented their proposal before the committee. The committee noted that this FDC is already approved by CDSCO in consultation with the SEC and now the firm has applied for additional indication for use against Novel Corona virus SARS-Cov-2. Committee also noted that this FDC is already approved by EPA of USA for use against Novel Corona virus SARS-Cov-2. After detailed deliberation committee recommended for grant of permission for manufacturing and marketing the product for the proposed additional indication.
SND Division			
4.	SND/CT/20/000021 Niclosamide IM injection	M/s Daewoong Pharmaceuticals Pvt. Ltd	In light of earlier 78th SEC meeting recommendation, the firm presented revised Phase I Protocol for conduct of Phase I , PK, PD and Safety study in healthy volunteers and status of Phase I study in South Korea. The firm presented their proposal for conduct of Phase I study in two part. Part A (Healthy volunteers) and Part B (Covid-19 Patients) After detailed deliberation committee recommended for grant of permission to conduct the Part A of the Phase I Clinical Trial The results of the Phase I Clinical Trial Part A should be submitted for further review by the committee.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
5.	SND/IMP/20/000198 Thymosin α-1 for injection 1.6 mg	M/s Gufic Biosciences Limited	The firm presented the proposal of Thymosin α-1 for injection 1.6 mg as an add on treatment in moderate to severe COVID-19 patients along with SoC treatment and requested for clinical trial waiver. After detailed deliberation the committee recommended that firm should conduct Phase III clinical trial. Accordingly, firm should submit protocol with justified sample size for review by the committee.