Recommendations of the SEC (Cardiovascular & Renal) made in its 110th meeting held on 22.09.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/21/000031 Tafamidis soft Gelatin Capsules 61 mg	M/s. Pfizer	The firm has presented the proposal for conduct of the active surveillance study before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed active surveillance study with the drug as per the protocol presented subject to the condition that the firm should include more government sites & the results of the study should be submitted to CDSCO for review by the committee.
2.	ND/IMP/21/000085 Finerenone 10mg & 20mg Film coated Tablets	M/s Bayer Pharmaceuticals Pvt. Ltd.	The firm presented their proposal for amendment in the warning statement of Finerenone 10mg & 20mg Film coated tablets before the committee. After detailed deliberation, the committee recommended for amendment in the warning statement as "To be sold by retail under the prescription of Nephrologist/ Cardiologist /Consultant Physician/ Diabetologist only".
FDC Division			
3.	FDC/MA/22/000242 Bisoprolol Fumarate IP 5mg/2.5mg+ Cilnidipine IP 10mg/10mg tablets	M/s. Ajanta Pharma Ltd.	The firm presented their proposal along with BE study protocol. After detailed deliberation, the committee recommended for conducting the BE study. The BE study results should be presented before the committee along with Phase III CT study protocol for further consideration.
4.	FDC/MA/22/000259 Cilnidipine IP 20mg +Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (As ER) 50mg Tablets	M/s. Ajanta Pharma Ltd.	The firm didn't turn up for presentation.
5.	FDC/MA/22/000064 Ezetimibe10mg +	M/s. Windlas Biotech Ltd.	Inlight of earlier recommendation dated 27.04.2022, the firm presented BE study report before the committee.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Rosuvastatin 20mg tablets		After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with the condition that the firm should submit the Phase IV Clinical trial protocol within 03 months from the date of approval to CDSCO. The protocol shall be presented before the committee for review.
6.	FDC/MA/21/000007 Ivabradine HCl eq. to Ivabradine 5mg/5mg+Metoprolol Tartrate 50mg/25mg tablets	M/s. Pure & Cure	The firm didn't turn up for presentation