Recommendations of the SEC (Ophthalmology) made in its 46th meeting held on 25.06.2021 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory remarks			
		New Drug Division	
1.	ND/MA/20/000176- Lifitegrast 5% eye Drops	M/s Micro Labs Limited	The Firm presented their proposal of Phase- III clinical trial protocol before the committee. After detailed deliberation, the committee recommended or grant of permission to the conduct of Phase- III clinical trial of the drug as per clinical trial protocol presented before the committee.
		Biological Division	
2.	BIO/CT/21/000022- Bevacizumab solution for injection 5.75 mg/0.23 ml	M/s Intas Pharmaceuticals Ltd	In light of the earlier SEC recommendation dated 31.10.2019 and SEC meeting dated 23.02.2021& 24.02.2021, firm presented the animal toxicity data in rabbits and protocol for conduct of Phase III with waiver of phase-I and II clinical trial. The committee noted that the drug is not approved for the proposed indication anywhere in the world and also administered through a new route. After detailed deliberation, the committee recommended that the firm should demonstrate the safety and adequacy of the dose through initial phase clinical studies before carrying out Phase III clinical trial.
3.	BIO/CT21/BO2021/24725- Ranibizumab	MsLupin	The firm presented the proposal for marketing authorization based on the results of Phase III multicentre clinical trial conducted in the country. After detailed deliberation the committee recommended for grant of approval for marketing, subject to the following condition 1.The specifications of the drug should be equivalent to the reference product. 2.The firm shall submit Phase IV clinical trial protocol within three months of the grant of marketing authorization.

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SND Division			
4.	SND/CT/21/000021 Atropine Sulfate Ophthalmic Solution	M/s Sun Pharma	The firm presented the Phase IV Clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the protocol presented subject to condition that there should be increase in the sample size to cover for drop out.
5.	SND/IMP/21/000012 Cyclosporine Ophthalmic Solution 0.09% w/v	M/s Sun Pharma	The Firm presented the proposal for Cyclosporine Ophthalmic Solution 0.09% w/v (Additional strength) After detailed deliberation, the committee recommended for grant of permission subject to the condition to conduct Phase IV Clinical trial. Accordingly, the firm should submit Phase IV Clinical trial Protocol for review by the committee.
6.	SND/CT/20/000269 Riboflavin Sodium Phosphate IP eq. to Riboflavin 0.1 % w/v Ophthalmic Solution for PFS (pack size is 3.0 ml)	M/s Sunways Limited	In light of the earlier SEC recommendation dated 23.02.2021&24.02.2021, the firm presented their proposal along with justification and data submitted for Riboflavin Sodium Phosphate IP eq. to Riboflavin 0.1 % w/v Ophthalmic Solution for PFS (pack size is 3.0 ml) for already approved indication.(Additional pack size) After detailed deliberation, the committee recommended for the grant of permission for manufacturing of the product.
7.	SND/IMP/20/000106 Hydroxypropyl methylcellulose	M/s Medsyn Therapeutics	Firm presented their proposal for import and marketing of Hydroxypropyl methyl cellulose 2.3% w/v ophthalmic solution (additional strength) along with local clinical trial waiver. After detailed deliberation, the committee recommended for the grant of permission for import and marketing of the Hydroxypropyl methyl cellulose 2.3% w/v ophthalmic solution (additional strength).
FDC Division			
8.	FDC/MA/18/000081 Timolol maleate IP eq. to Timolol 5mg + Travoprast 40ug eye drop	M/s. Akums Drugs & Pharmaceuticals	The firm presented the ocular toxicity study data along with phase III clinical protocol before the committee. The Committee noted that firm has not conducted ocular toxicity study in a GLP compliant facility.

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			As regard to Phase III trial protocol, committee found it adequate. After detailed deliberation, the committee recommended that firm should initially conduct repeated dose toxicity study in a GLP compliant facility and present the results for further consideration.
9.	FDC/IMP/21/000009 Carbomer 980 -0.2%w/v + Sodium Hyaluronate 0.2% w/v EP	M/s. Medicom	The firm presented their proposal along with phase III clinical trial waiver before the committee. The committee noted that the proposed product is approved in UK. However, the firm didn't present any safety and efficacy data including the data generated within Indian Population. After detailed deliberation, the committee recommended that the firm should present the above data for further consideration by the committee.
10.	FDC/MA/21/000116 Netarsudil 0.02% w/v + Timolol 0.5% w/v Ophthalmic Solution	M/s Ajanta Pharma Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed phase III clinical trial. The results of the study should be presented before the committee.
Medical Device Division			
11.	CI/IVD/2021/37700 TeaRx diagnostic Kit for Dry Eye	M/s LV Prasad Research Foundation, Hyderabad Telangana	The applicant presented their proposal of academic clinical performance evaluation. After detailed deliberation, the committee recommended for grant of permission to conduct the academic clinical performance study as presented. Note:-The outcome of the study shall not be used for any regulatory approval. .