Recommendations of the SEC (Ophthalmology) made in its 66th meeting held on 25.05.2023 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2023/ 36191 Aflibercept 40mg/mL	M/s. Zydus Life Sciences Limited	The firm presented the protocol for conduct of Phase III clinical trial titled "A Phase III, randomized, double blind, parallel group, multi-center study to compare the efficacy, safety and immunogenicity between test Aflibercept and Eylea®in patients with neovascular (Wet) age-related macular degeneration (AMD)" as per protocol No. AFLI.22.001 version 01. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial with following changes in the presented protocol. 1. In the inclusion criteria, Sr. No. 09 needs to be clearly defined with respect to female participants. The wording should be that women who have attained menopause should be included instead of a female participant is eligible to participate if she is not pregnant or breast feeding, etc. 2. The firm should provide standard of care to the study subject for the other eye which is not under studies during the trial. Accordingly, the firm should submit revised protocol to CDSCO.
SND Division			
2.	SND/MA/20/000103 Cetirizine Ophthalmic Solution 0.24% w/v	M/s. Akums	In light of the earlier SEC recommendation dated 20.02.2020 firm presented the Phase III clinical trial protocol. After detailed deliberation, the committee recommended as follows: 1) The firm should include reference arm with standard of care. 2) The sample size should be recalculated and firm should submit justification for the same. Accordingly, the firm should submit the

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			revised clinical trial protocol to CDSCO for further review by the committee.
FDC Division			
3.	FDC/CT/23/000001 Ketorolac 0.3% + Phenylephrine1.0% Intraocular Solution	M/s. COD Research Pvt. Ltd.	The firm presented the proposal before the committee along with request for deliberation of Phase II clinical trial protocol. After detailed deliberation, the committee recommended that firm should present the ocular toxicity study data, rationale justification for adding Sodium Hydroxide NF & Hydrochloric Acid NF along with active ingredients and include the following points in Phase II protocol: 1. Rescue medication should be included. 2. The surgical technique should be standardized for all. The same viscoelastic substances should be used by all surgeons. 3. The pain score should be recorded with information about the pain killers taken in the 4 week post-operative period. 4. Safety profile like corneal endothelium damage should be included & it should be pre and post procedural macular OCT. 5. Standard statistical procedure should be adopted. In view of above, firm should revise the protocol and submit the justification to CDSCO for further review by SEC.
4.	FDC/MA/22/000252 Ketorolac tromethamine IP eq. to Ketorolac 3mg +Phenylephrine HCl IP Eq. to Phenylephrine 10mg1.0% Intraocular Solution	M/s. Aurolab	The firm did not turn up for presentation.

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GCT Division			
5.	CT/62/17 Online Submission (24349) LUBT010 with Lucentis®	M/s. Lupin	The firm presented protocol amendment, protocol No. LRP/LUBT010/2016/008, version number 3.0 (India specific) dated 13.02.2023. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
6.	CT/49/22 Online Submission (24284) AVT06	M/s. IQVIA	The firm presented protocol amendment, for protocol No. AVT06-GL-C01, version 3.0 dated 21.10.2022. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.