

Ophthalmic Devices Panel of the Medical Devices Advisory Committee Meeting November 10, 2022 FDA Virtual Meeting 10903 New Hampshire Avenue Silver Spring, MD 20993

As required by section 513(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) is convening the Ophthalmic Devices Advisory Panel for the purposes of obtaining recommendations about the classification of ophthalmic dispensers.

FDA is holding this panel meeting to obtain input on the risks and benefits of ophthalmic dispensers. The Panel will be asked to recommend to FDA whether these devices should be classified into Class I (subject only to General Controls). If there is disagreement with FDA's proposed classification, the Panel will be asked to discuss the rationale for recommending a different classification, including the appropriate controls necessary to mitigate risks to health and assure the safety and effectiveness of these devices.

AGENDA

9:00 a.m.	Call to Order, Opening Remarks and Introduction of the Committee	Neil Bressler, MD
9:10 a.m.	Conflict of Interest Statement	Jarrod Collier, MS
9:15 a.m.	Open Public Hearing	Jarrod Collier, MS
10:15 a.m.	FDA Presentation - Classification Overview	Linh Lo, PhD
10:25 a.m.	FDA Presentation - Ophthalmic Dispensers (LXQ)	Elissa Wong, PhD
10:55 a.m.	Panel Deliberations	Neil Bressler, MD
11:40 a.m.	Panel Q&A	Neil Bressler, MD
12:10 p.m.	FDA Summation	Tieuvi Nguyen, PhD
12:15 p.m.	Proceedings Adjourned	Neil Bressler, MD