FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Brief Summary of the Ophthalmic Devices Panel Meeting November 10, 2022

Introduction:

The Ophthalmic Devices Panel of the Medical Devices Advisory Committee for the Food and Drug Administration met on November 10, 2022 to discuss and make recommendations on the classification of ophthalmic dispensers, which are currently unclassified pre-amendment devices, to class I (general controls). This included a discussion of the known risks and safety/effectiveness concerns and a general classification recommendation for ophthalmic dispensers.

Panel Deliberations/FDA Questions:

1. **Please comment on whether you agree with the inclusion of all the risks in the overall risk assessment of ophthalmic dispensers under product code "LXQ." In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these ophthalmic dispensers.**

The Panel discussed the following FDA-identified risks to health for ophthalmic dispensers:

- Infection
- Adverse Tissue Reaction
- Compromised Treatment
- Mechanical Injury

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of ophthalmic dispensers. The Panel agreed that the risks seem appropriate as currently identified and should be interpreted as low risk. The Panel also expressed a concern related to the potential risk of users confusing different dispensers that look similar but that are not for use on the eye from those that are for ophthalmic use.

2. **Please discuss whether you agree with FDA's proposed classification of Class I for ophthalmic dispensers under the product code "LXQ." If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.**

The Panel agreed that ophthalmic dispensers would appropriately be regulated as Class I devices and that general controls are sufficient to address the identified risks. The Panel recommended that eye cups and droppers be distinguished, as the degree of risks for these devices may be different. For example, regarding the sterility of eye cups as compared to droppers, the Panel discussed that there was less concern regarding the sterility of eye cups as compared to sterility of droppers, given that droppers can store ophthalmic medications that are used repeatedly over time, while eye cups are not intended for this purpose.

The Panel also recommended that FDA consider additional clarification into the language of the identification of the regulation for ophthalmic dispensers to make it clear that these devices are empty containers and that they are for external/topical use only. Lastly, the Panel recommended that the FDA consider what safeguards may need to be in place to address safety issues potentially related to ophthalmic dispensers that are intended to be used with solutions containing preservatives or potential concerns regarding multi-use dispensers as compared to single use dispensers.

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Transcripts may be downloaded from:
November 10, 2022: Ophthalmic Devices Panel of the Medical Devices Advisory Committee Meeting Announcement

OR

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