FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) Meeting
October 30, 2026

QUESTIONS

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1. **DISCUSSION:** The robustness of the primary efficacy results from Study SYD-101-001, considering the borderline statistical significance and the impact of missing data on the reliability of the findings.

2. **DISCUSSION:** The clinical meaningfulness of the observed efficacy profile, taking into account the magnitude of the treatment effect on spherical equivalent, the declining treatment trajectory over time, and the lack of a significant effect on axial length.

3. **DISCUSSION:** How the descriptive and exploratory subgroup analyses (e.g., children aged 3 to ≤12 years and fast progressors) contribute to a determination of effectiveness.

4. **DISCUSSION:** Whether the published literature provides sufficient corroboration to satisfy the substantial evidence standard for approval.