

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

Dermatologic and Ophthalmologic Drugs Advisory Committee (DODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
October 13, 2017

DRAFT QUESTIONS

1. **VOTE:** Do the clinical trials support the efficacy of netarsudil ophthalmic solution for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension?
 - a. If no, what additional trials would you recommend?

2. **VOTE:** Does the efficacy of netarsudil ophthalmic solution, demonstrated in the clinical trials, outweigh the safety risks identified for the drug product?
 - a. If no, what additional trials would you recommend?

3. **DISCUSSION:** Please discuss any suggestions you have concerning the proposed draft labeling of the product.