

OPHTHALMIC DRUGS
SUBCOMMITTEE

JULY 21, 1999

CYCLOSPORINE NDA 21023

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FDA BRIEFING PACKAGE



Food and Drug Administration
Rockville MD 20857

June 23, 1999

To Advisory Committee Meeting Participants:

This document is the FDA's Action Package for the Ophthalmic Drugs Subcommittee Meeting for July 21, 1999, on Allergan's Cyclosporine, NDA 21-023.

The following items are contained:

1. Draft questions for discussion at the meeting.
2. The Agency's Medical Officer Draft Review for NDA 21-023.
3. The Agency's Statistical Review for NDA 21-023.

Please direct any questions concerning the meeting to Jayne Peterson at (301) 827-7001.

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ADVISORY COMMITTEE
QUESTIONS

Draft Advisory Committee Questions:

1. Has sufficient evidence been submitted to support the efficacy of cyclosporine ophthalmic emulsion for the treatment of keratoconjunctivitis sicca? Are additional studies needed to establish efficacy for this product?
2. Are there adverse experiences that are of particular concern for this product? Are additional studies needed to further quantify/qualify these experiences?
3. Are additional studies needed to establish the safety of this product?
4. Other issues related to the safety or efficacy of the product?
5. Does the committee recommend approval of cyclosporine ophthalmic emulsion for the treatment of moderate to severe keratoconjunctivitis sicca?