Food and Drug Administration
Center for Drug Evaluation and Research

Dermatologic and Ophthalmic Drugs Advisory Committee

November 4-5, 2002

Recommendations for the development of a proposed draft guidance concerning the development of products for mild to moderate acne vulgaris

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Questions to the Committee

1. Should the current success criteria using the co-primary endpoints be retained?

2. How should lesion counts be analyzed?

3. What investigators' global severity scale should be used? At what level should it be dichotomized into success and non-success?

3. Should acne lesion types (inflammatory or noninflammatory) be medically acceptable indications?

5. Should lesion counts be assessed at multiple time-points late in the study and averaged to increase power?

6. How should the efficacy outcomes of clinical trials be portrayed in labeling to be maximally useful to clinicians and patients? What graphics and tables should be provided?
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