

CENTER FOR DRUG EVALUATION AND RESEARCH

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STATISTICAL REVIEW(S)



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmacoepidemiology and Statistical Science
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/Serial Number: 50-805 / 000

Drug Name: OraceaTM (doxycycline _____ capsules)
40 mg

Indication(s): Inflammatory Lesions of Rosacea

Applicant: Collagenex Pharmaceuticals, Inc.

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