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*APPLICATION NUMBER:*

**50-805**

**MEDICAL REVIEW**

## CLINICAL REVIEW

Application Type NDA 505(b)(1)  
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Reviewer Name Patricia Brown, MD  
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Established Name Doxycycline  
(Proposed) Trade Name (Oracea™)  
Therapeutic Class Rosacea product  
Applicant CollaGenex Pharmaceuticals

Priority Designation S

Formulation Capsule 40mg  
Dosing Regimen Once Daily in morning  
Indication — Inflammatory Lesions  
(Papules and Pustules) of Rosacea  
in Adult Patients  
Intended Population Men and Women 18 years and  
older

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Clinical Review  
Patricia C. Brown, MD  
NDA 50-805  
Oracea™ (doxycycline, USP) 40 mg capsules

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