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APPLICATION NUMBER:

207154Orig1s000

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type NDA
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Reviewer Name(s) Patricia C. Brown, MD
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Established Name Dapsone gel, 7.5%
(Proposed) Trade Name ACZONE® Gel, 7.5%
Therapeutic Class Acne agent
Applicant Allergan, Inc.

Formulation(s) Gel
Dosing Regimen Once daily
Indication(s) Topical treatment of acne
vulgaris
Intended Population(s) Patients 12 years of age and
older

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