CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

207154**Orig1s000**

Trade Name:	Aczone
Generic or Proper Name:	Dapsone Gel 7.5%
Sponsor:	Allergan, Inc.
Approval Date:	February 24, 2016
Indication:	For topical treatment of acne vulgaris in patients 12 years of age and older.

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207154Orig1s000

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207154

NDA APPROVAL

Allergan, Inc.
Attention: Jeremy McCumber, MS
Director, Global Regulatory Affairs
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

Dear Mr. McCumber:

Please refer to your New Drug Application (NDA) dated and received April 28, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ACZONE (dapsone) Gel, 7.5%.

This new drug application provides for the use of ACZONE (dapsone) Gel, 7.5% for the topical treatment of acne vulgaris in patients 12 years of age and older.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels, except with the revisions listed below, as soon as they are

available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 207154**." Approval of this submission by FDA is not required before the labeling is used.

Revise the carton and immediate container labels to reflect "Gel" (not "gel") for consistency with the content of labeling.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 8 years 11 months because necessary studies are impossible or highly impracticable. This is because acne is extremely uncommon in pediatric patients below 9 years of age.

We are deferring submission of your pediatric study for ages 9 to 11 years 11 months for this application because this product is ready for approval for use in adults and adolescents ages 12 years and above and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the FDCA. This required study is listed below.

3017-1 Conduct an open-label study to assess safety, pharmacokinetics, and treatment effect of ACZONE (dapsone) Gel, 7.5% in 100 pediatric subjects aged 9 years to 11 years 11 months with acne vulgaris. Pharmacokinetic assessments will be done in at least 16 evaluable subjects under maximal use conditions.

Final Protocol Submission:	06/2016
Study Completion:	03/2019
Final Report Submission:	11/2019

Submit the protocol(s) to your IND 054440, with a cross-reference letter to this NDA.

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