CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207154Orig1s000

CHEMISTRY REVIEW(S)

Memorandum

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: **February 17, 2016**
From: **Yichun Sun, Ph.D.**
Application Technical Lead, Branch V
Division of New Drug Products II
Office of New Drug Products

Through: **Moo-Jhong Rhee, Ph.D.**
Chief, Branch V
Division of New Drug Products II
Office of New Drug Products

To: CMC Review #1 of NDA 207154

Subject: Final Approval Recommendation for NDA 207154

At the time when the CMC review #1 was written, resolution of issues on Labels and Labeling was pending.

Label/Labeling

On February 11, 2016, the NDA applicant submitted an amendment providing the finalized mock up container and carton labels. Additionally, the applicant also agreed to all the CMC changes made to the package insert. All the labels/labeling issues are now satisfactorily resolved. The review of the CMC sections of the final package insert, and mock up container and carton labels was conducted by Dr. Hitesh Shroff is attached (**Attachment - 1**).

Recommendation:

The revised package insert and mock-up container and carton labels are acceptable from the CMC perspective. Therefore, from the ONDP's perspective, this NDA is recommended for **APPROVAL**. An expiration dating period of 24 months is granted for the drug product of NDA 207154.

Application Technical Lead's Assessment and Signature

The NDA is recommended for approval from quality perspective.

Yichun Sun, Ph.D.
Application Technical Lead, Branch V
Division of New Drug Products II
2/17/2016

Yichun Sun -S

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Date: 2016.02.17 14:21:13 -05'00'

Attachment - 1 (Review of CMC Sections of the Finalized Labeling and Labels)

Memorandum

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: **February 17, 2016**

From: **Hitesh Shroff**
Senior CMC Reviewer
DNDP II/ONDP

Hitesh N. Shroff -S

Digitally signed by Hitesh N. Shroff -S
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Date: 2016.02.17 12:20:39 -05'00'

Through: **Moo-Jhong Rhee, Ph.D.**
Chief, Branch V
DNDP II/ONDP

To: **CMC Review #1 of NDA 207154**

Subject: **Final Approval Recommendation**

The CMC review #1 has noted the following pending issues:

- The label/labeling issues were not completely resolved.

Because of these deficiencies, in the CMC review #1, this NDA was not recommended for approval from the CMC perspective.

The package insert and the container and carton labels have been revised and submitted on February 11, 2016. The labels/labeling are revised satisfactorily from the CMC perspective (**Attachment 1**).

Recommendation:

This NDA is now recommended for approval from the ONDP perspective.

1. *Package Insert*

(a) "Highlights" Section

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ACZONE® Gel, 7.5% safely and effectively. See full prescribing information for ACZONE® Gel, 7.5%.

ACZONE® (dapsone) Gel, 7.5%, for topical use
Initial U.S. Approval: 1955

DOSAGE FORMS AND STRENGTHS
Gel, 7.5% (3).

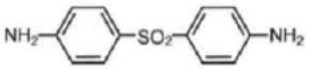
(b) "Full Prescribing Information" Section

#3. Dosage Form and Strength

3 DOSAGE FORMS AND STRENGTHS
Gel, 7.5%. Each gram of **ACZONE Gel**, 7.5% contains 75 mg of dapsone in an off-white to yellow gel with suspended particles.

#11. Description

11 DESCRIPTION
ACZONE (dapsone) Gel, 7.5%, contains dapsone, a sulfone, in an aqueous gel base for topical dermatologic use. **ACZONE** Gel, 7.5% is an off-white to yellow gel with suspended particles. Chemically, dapsone has an empirical formula of $C_{12}H_{12}N_2O_2S$. It is a white or slightly yellow-white, crystalline powder that has a molecular weight of 248.30. Dapsone's chemical name is 4-[(4-aminobenzene) sulfonyl] aniline and its structural formula is:



Each gram of **ACZONE** Gel, 7.5%, contains 75 mg of dapsone, USP, in a gel of diethylene glycol monoethyl ether, methylparaben, acrylamide/sodium acryloyldimethyl taurate copolymer, isohexadecane, polysorbate 80, and purified water.

#16 How Supplied/storage and Handling

16 HOW SUPPLIED/STORAGE AND HANDLING

ACZONE Gel is an off-white to yellow gel with suspended particles. It is supplied in an airless pump containing a polypropylene bottle with a high density polyethylene piston.

ACZONE (dapsone) Gel, 7.5%, is supplied in the following sizes:

NDC 0023-5206-30	30 gram pump
NDC 0023-5206-60	60 gram pump
NDC 0023-5206-90	90 gram pump

Storage: Store at 20°C-25°C (68°F-77°F), excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature]. Protect from freezing.

5 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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