JOHNSON & JOHNSON CONSUMER INC.

SUMMARY CLINICAL STUDY REPORT

PROTOCOL TITLE:	A Single Center, Monadic, Open Label, Four-Week Clinical Trial to Evaluate the Tolerance and Efficacy of a Polymeric Surfactant Technology Cleanser in Sensitive Skin Patients
PROTOCOL NUMBER:	CCSSKA004090 Protocol Final Version 1.0 10SEP2021
DOCUMENT DATE:	18NOV2022
SITE STUDY NUMBER:	DCS-77-21
SPONSOR:	Johnson & Johnson Consumer Inc.
STUDY SITE:	Dermatology Consulting Services, PLLC
PRINCIPAL INVESTIGATOR:	Zoe Diana Draelos, M.D.
KEY STAFF:	*Site* Principal Investigator: Zoe Diana Draelos, MD Study Coordinator: Crystal Williams *Sponsor* Designated Physician Representative: Valerii Korzh, MD Study Director: Rabab Hussian, Pharm.D. Study Manager: Heather Smith Department Head: Karen Meyer
STUDY INITIATION DATE (First Subject First Visit):	25OCT2021
STUDY COMPLETION DATE (Last Subject Completed):	30NOV2021
SITE APPROVAL:	See trial master file for final clinical study report and approvals
SPONSOR REVIEW AND APPROVAL:	See trial master file for final clinical study report and approvals

The principles of the International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP E6 (R2)) were applied to this study.

INTRODUCTION	Cleansing is an important hygiene activity, necessary to prevent bacterial, fungal, yeast, and viral infection. However, in the presence of skin disease, cleansing can take on a new challenge. This challenge involves removing the sebum, sweat, externally applied substances, environmental debris, and organisms from the face without damaging the skin barrier. Since cleansers cannot easily distinguish between sebum and the intercellular lipids required to maintain skin integrity, unique cleansing technologies are necessary to provide mild cleansing for the many manifestations of sensitive skin. This research evaluates the appropriate of a cosmetic facial cleanser with polymeric surfactant technology in a population of subjects with sensitive skin due to presence of eczema/atopic dermatitis, rosacea, acne, or cosmetic intolerance syndrome.
OBJECTIVE	The study objective was to evaluate the efficacy and tolerance of a gentle facial cleanser in subjects with sensitive skin (eczema/atopic dermatitis, rosacea, acne, cosmetic intolerance syndrome).
STUDY DESIGN	Single Center, Monadic, Open Label, Four-Week Clinical Trial.
SUBJECT INFORMATION	The complete eligibility criteria for this study were followed as defined in the study protocol referenced on page 1 of this report.
INVESTIGATIONAL STUDY MATERIAL	A non-marketed cosmetic facial cleanser, F #14159-68.
DOSE AND MODE OF APPLICATION	Apply twice daily to cleanse facial skin. Wet Face. Apply to hands, add water and work into a lather. Massage face gently. Rinse.
METHODOLOGY	Tolerability and efficacy were measured by Investigator assessment and subject assessment for tolerability and efficacy. Photography (right, left, and frontal face with standard lighting 1 and cross polarized light), noninvasive assessments: Trans Epidermal Water Loss (TEWL), pH, triplicate corneometry, biomarker tapes, facial swabbing and subject questionnaire.
MEASUREMENT AND/OR EVALUATION SCHEDULE	The following were completed at all visits: • Investigator assessment for tolerability • Investigator assessment for efficacy • Subject assessment for tolerability • Subject assessment for efficacy • Photography (right, left, and frontal face with standard lighting 1 and cross polarized light) • Noninvasive assessments: TEWL, pH, triplicate corneometry • Biomarker Tapes • Facial Swabbing
INSTITUTIONAL REVIEW BOARD (IRB)	This study was reviewed and approved by the following IRB/IEC: - Name: Advarra Institutional Review Board (IRB) - Approval date: 01OCT 2021
SAFETY AND ADVERSE EVENTS	All Adverse Events (AEs/SAEs) were collected regardless of causal relationship to the subject's participation in the study. The information was collected/reported within the reporting timelines specified in the protocol.
MONITORING, QUALITY CONTROL, AND QUALITY ASSURANCE	The study monitoring was conducted as per the Sponsor´s requirements. The Study Site was/is subject to review by the IRB, to quality assurance audits

	performed by the Sponsor, and/or to inspection by appropriate regulatory authorities. Sponsor representatives and study site personnel completed a virtual site initiation meeting on 23SEP 2021.
OVERALL CONCLUSIONS	Overall results from this single-center, monadic, open label clinical trial indicate that the Sponsor's test material (Facial Cleanser F#14159-68), a gentle facial cleanser with polymeric surfactant technology, was well tolerated and effective in improving the cosmetic appearance of facial skin conditions when used over the course of 4 weeks by a population of subjects with sensitive skin due to presence of eczema/atopic dermatitis, rosacea, acne, or cosmetic intolerance syndrome, under the conditions of this test. Summary of results are presented as follows: for three skin conditions combined (eczema/atopic dermatitis, rosacea, and cosmetic intolerance syndrome combined), along with all skin conditions combined. **Summary of results for three skin conditions combined (eczema/atopic dermatitis, rosacea, and cosmetic intolerance syndrome combined) and for all skin conditions combined:** Results of the investigator observed tolerability parameters showed no statistically significant change (increase or decrease) in scores for any parameter (redness/erythema, rash/irritation, peeling/flaking, tactile roughness, or dryness) at week 2 or week 4 when compared with baseline. For the subject observed tolerability parameters, there was a statistically significant decrease (improvement) in scores for all parameters (stinging, burning, itching, tightness, redness, flaking/peeling, roughness, dryness, and overall sensitivity) at week 2 and week 4 when compared with baseline. Results of the investigator observed efficacy parameters showed a statistically significant decrease (improvement) in scores for issues with visual smoothness, tactile softness, clarity, radiance, and overall skin appearance at week 2 and week 4; and in scores for issues with pores at week 4 when compared with baseline. For the subject observed efficacy parameters, there was a statistically significant decrease (improvement) in scores for issues with all parameters (smoothness, softness, clarity, radiance, pores, and overall skin appearance) at week 2 and week 4 when compared with baseline. Analysis of the questionnaire indicated that a statistically significantly greater proportion of subjects selected favorable responses to 15 out of 17 inquiries (regarding application experience, improvements in skin appearance and feel, etc.) after 4 weeks of using the facial cleanser.

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