COMPARATIVE ASSESSMENT OF TWO EYE AREA COSMETIC FORMULATIONS THROUGH EVALUATION OF ALTERNATIVE EYE IRRITATION METHODS RELATIVE TO ENDPOINTS MEASURED IN A HUMAN CLINICAL SUB-ACUTE STUDY DESIGN

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ABSTRACT

Evaluating ocular irritation of eye area formulations is essential to their development and acceptance by consumers. Alternative methods for assessing eye irritation have been developed as a tool to evaluate formulations, which has been driven by the inability to develop non-invasive, human clinical evaluations. In vitro methods have been developed and validated as a means to determine the potential ocular irritation of a formulation, which can help to identify formulations that may be unacceptable to consumers. This study evaluated two similar formulations by comparing alternative methods consisting of in vitro evaluations and human clinical evaluations. RESULTS: This study demonstrates the need to consider a wide range of evaluation methods to determine the potential ocular irritation of eye-area formulations. Although eye(area formulations are designed to be non-irritating to human clinical evaluations, they may still cause mild, subjective/objective ocular responses that can limit their acceptability. In vitro evaluations are useful to predict the potential ocular irritation of a formulation, but they should be supplemented with human clinical evaluations to ensure that formulations are safe and acceptable to consumers. These studies demonstrate the need to evaluate formulations using a combination of in vitro and human clinical evaluations to ensure that they are safe and acceptable to consumers.