U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL MEMORANDUM

NDA #:	208,144
Product Name:	Luminesse (brinonidine tartrate ophthalmic solution, 0.025%)
Indication(s):	Relief of redness of the eye due to minor eye irritations
Applicant:	Bausch+Lomb
Dates:	Stamp date: February 27, 2017 PDUFA date: December 27, 2017 Review completion date: October 30, 2017
Review Priority:	Standard
Biometrics Division:	Division of Biometrics VII
Statistical Reviewer:	Joo-Yeon Lee, Ph.D
Concurring Reviewers:	Rima Izem, Ph.D
Medical Division:	Division of Nonprescription Drug and Products
Clinical Team:	Jenny Kelty, MD Steve Osborne, MD
Project Manager:	LCDR Jung E. Lee, RPh

1. BACKGROUND

The document reviewed in this memorandum is a new drug application resubmission after the sponsor received a Refusal to File (RTF) letter on the original submission on May 29, 2015. The main reason for RTF was that the sponsor failed to provide post-marketing data critical for an adequate safety review of the proposed product for use in the OTC consumer population.

The focus of this statistical memorandum is review of the label interpretation study. The sponsor conducted this consumer behavior study to examine how consumers interpret a specific therapeutic claim on the Principal Display Panel (PDP) of [redacted] (b) (4) ', and to determine if consumer understand the phrase '[redacted] (b) (4) ' to 'redness relief'. Please refer to Amanda Pike-McCrudden's review for details on study design and a qualitative evaluation of the data.

2. SUMMARY OF THE STUDY

Study Design: The study was a multi-site, single visit, label interpretation study in a general population who were at least 18 years of age.

[redacted] (b) (4)

3. STATISTICAL COMMENTS

We could reproduce the sponsor's primary and subgroup analyses results. We noted that the sponsor's report did not provide details on subject disposition. Therefore, it is not clear how many subjects were screened and whether all those screened completed the study.

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/s/

JOO YEON LEE
10/30/2017

RIMA IZEM
10/31/2017