BAUSCH + LOMB

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

October 19, 2012

Re: Docket No. FDA–2012–N-0892, Communicating Composite Scores in Direct-to-Consumer (DTC) Advertising

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Dear Sir or Madam:

Reference is made to the August 23, 2012 Federal Register (Vol. 77, 51027-51030) whereby the Agency requested comments on research entitled "Communicating Composite Scores in Direct-to-Consumer (DTC) Advertising." This study is intended to explore how consumers understand and interpret composite endpoint scores in DTC advertising (ads).

Bausch + Lomb is one of the best-known and most respected healthcare companies in the world. Our core businesses include contact lenses and lens care products, ophthalmic surgical devices and instruments, and ophthalmic pharmaceuticals. Founded in 1853, our company is headquartered in Rochester, N.Y., and employs more than 10,000 people worldwide. Our products are available in more than 100 countries.

Bausch + Lomb appreciates the opportunity to provide comments on this proposed study and supports the FDA in its efforts to enhance consumer comprehension of direct-to-consumer (DTC) prescription drug promotion. In consideration of the agency and participant resources, the following comments and recommendations are provided.

A. Usefulness of the proposed collection of information (study)

In the Federal Register notice, FDA intends to assess through two surveys how consumers understand a composite score representing prescription product's efficacy as explained in DTC consumer advertisement. Bausch + Lomb supports enhancing consumer comprehension, including an understanding and interpretation of composite scores, but believes this specific study[1] as proposed may not be necessary to achieve the intended goal when taking the preliminary research findings by FDA into account.

In the Federal Register notice, FDA stated[2] that research on composite scores is scant, few participants in the focus group study conducted in September 2011 had heard of the term, and none were aware how the scores might be used in clinical trials. The focus group study revealed that some participants felt that adding more statistical

[1] Comprised of two separate questionnaires
[2] Federal Register notice, page 51028, first column

details would make the ads more complicated, thus decreasing the likelihood that consumers would read them. Thus, FDA has already established through a limited focus group and literature[3] that there is little understanding of composite scores and adding additional information would reduce the value of the information. Furthermore:

- Considering a healthcare practitioner (HCP) prescribes based on an interaction between the HCP and the patient (which may include a discussion of symptoms and appropriate treatment choices) and the objective of the Brief Summary[4], a lack of comprehension of composite scores by the consumer can be lessened through the HCP/patient interaction[5,6] and review of the Brief Summary.

- The meaning of an indication stated as a composite endpoint for medical conditions considered life-threatening or debilitating[7] can vary considerably from those presented for seasonal nasal allergies and therefore, results from the proposed study associated with nasal allergies applied broadly to all prescription products with complex composite efficacy score may not be understood in the same manner by the consumer.

Recommendation to enhance consumer comprehension of composite scores

In January 2004, FDA issued Draft Guidance for Industry "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements", in May 2011, FDA completed the "Evaluation of Format and Content in the Brief Summary in Print Ads"[8], and in July 2011, FDA announced the "Experimental Study of Format Variations in the Brief Summary of Direct-to-Consumer (DTC) Print Advertisements" (Expected completion date: 2013). Each of these is intended to enhance the utility of the Brief Summary and while the intent of the Brief Summary is to facilitate the communication of important safety information, it also makes available other important information. Of note, the Executive summary of the "Evaluation of Format and Content in the Brief Summary in Print Ads" states, "… results also demonstrate that when people choose to

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[3] As per the Federal Register notice, p. 51028, 2nd column which states, "Second, although the literature tends to suggest limiting the amount of information presented in advertisements (Refs. 7 to 9), ..."

[4] Line 129-130 of the January 2004, FDA issued Draft Guidance for Industry "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements" also notes, "…FDA-approved patient labeling provides risk and benefit information that is material to the decision by the patient (with the involvement of a health care practioner) whether to use a prescription drug..." In addition, each brief summary in a DTC print ad includes statements that emphasize discussions with the healthcare provider or pharmacist.

[5] Section III Research Purpose states that the research will include "4…to maximize consumer comprehension and informed decisionmaking."

[6] Reference is made to Docket No. FDA-2012-N-0018 "Healthcare Professional Survey of Prescription Drug Promotion" which is intended to gain greater understanding of the HCP/patient relationship

[7] For example, a cardiovascular composite endpoint may include myocardial infarction, stroke, hospitalization for heart failure, and death.

[8] Results published June 2011 Randomized Trial of Risk Information Formats in Direct-to-Consumer Prescription Drug Advertisements, Kathryn J. Aikin, Amie C. O'Donoghue, John L. Swasy and Helen W. Sullivan, *Med Decis Making* published online 20 June 2011 with an Executive Summary available from http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm258483.htm

spend time reading the brief summary, they are able to understand the major risk concepts in the document, are more likely to choose additional topics of importance, and are more likely to try to find more information about the product. These findings are consistent with the basic idea that people who are more interested in an issue will spend more time thinking about and learning about that issue. We found no systematic differences across medical conditions, a finding that strengthens the applicability of these results."

While some level of uncertainty remains concerning the understanding of consumers in how they interpret the approved prescription drug indication based on composite scores, the Agency may consider leveraging the brief summary to improve consumer comprehension of composite scores. For example, FDA might recommend having three points in the Brief Summary guidance. First, an asterisk placed in the advertisement at the end of a composite endpoint statement. Secondly, a concise statement included in the Brief Summary which plainly explains "What does *{state verbiage of composite score]* mean? Finally, proposed text in the Brief Summary draft guidance, when final, as to what a composite endpoint score means. These recommendations would enhance awareness when a composite score is involved. Bausch + Lomb feels that type of educational intervention is supportive of FDA's intent without further burdening participants. Additionally, reissuance of a revised Brief Summary draft guidance based on the outcome of the "Experimental Study of Format Variations in the Brief Summary of Direct-to-Consumer (DTC) Print Advertisements" (Expected completion date: 2013) would allow for public input on any recommendations.

We respectfully request that the FDA reconsider whether the study as defined in the Federal Register notice is necessary to achieve its intended purpose, specifically in light of the findings from the focus group. We ask the FDA to consider alternative, less burdensome, approaches to enhance consumer understanding of composite scores.

B. Timely publication of the study status and results

Over the past years, the Agency has proposed various studies to enhance understanding of consumer and physician perception and comprehension of prescription drug advertising and promotion. To date, a strategic plan has not been published on how results will be collated and assessed across studies to guide future guidance development and/or regulatory requirements. In addition, while some studies have been completed, the data have not been made available on the OPDP Research webpage[9].

Recommendation to enhance transparency

Bausch + Lomb requests, for transparency, that FDA publish in a timely manner the detailed study status[10] and summary outcome for each of the advertising and promotion studies posted on the OPDP Research webpage. In addition, it is also requested that along with the study status, FDA publish a strategic plan that clearly shows which studies are discrete, which are interdependent or tangentially related to another study,

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[9] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm

[10] For example, "This study will be initiated mm/yyyy", "This study is targeted for completion mm/dd/yyyy", "Data are being assessed and expected to be available mm/yyyy"

and how data will be used (e.g., develop new guidance, update existing guidance, rulemaking, information only).

Bausch + Lomb believes doing so is consistent with FDA's stated goal for increased transparency[11] to industry and will greatly assist the public when assessing newly proposed studies related to consumer or healthcare professional understanding of advertising and promotion.

C. Assessment of effectiveness and risk recall of drugs– beyond the stated intent of the study

Section IV, Design Overview[12], Study 1 states, "Questions will also explore consumers' understanding of how the effectiveness of drugs is measured in general." Section IV, Design Overview, Study 2 states, "Outcome measures will include consumers' awareness and comprehension of the composite score concept, perceived drug efficacy, and risk recall." These queries appear to go beyond the stated intent of the study[13]. Furthermore, there is at least one other proposed study[14] explicitly designed to focus on comprehension of efficacy information in DTC ads.

Should this study proceed as proposed and not be revised based on Comment A above, Bausch + Lomb recommends that general and exploratory questions be removed from the proposed questionnaires since they are outside the intent of the stated study and may unnecessarily increase burden on participants and data assessment when this type of information is being collected elsewhere.

D. Other Media and Mobile Technologies This scope of this study is limited to DTC print ads and as such, we request that the results not be broadly applied to other forms of advertising such as websites[15], smart phones, social media, etc.

Bausch + Lomb supports the Agency in enhancing both consumer and healthcare professional understanding of DTC advertising trusts these comments and recommendations support the Agency's goals while also eliminating or reducing burden regarding the collection of information that may not be necessary.

Sincerely,

Kimberly Belsky
Executive Director, Policy and Communication
Global Pharmaceutical Regulatory Affairs

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[11] http://www.fda.gov/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/ExecutiveSummary/default.htm

[12] Federal Register notice, page 51028, 3rd column

[13] "This study is intended to explore how consumers understand and interpret composite endpoint scores in DTC ads."

[14] Reference is made to Docket No FDA-2010-N-0266 "Study of Clinical Efficacy Information on Professional Labeling and DTC Print Advertisements for Prescription Drugs" with the expected completion date of 2012.

[15] Which includes the ability to manage information through electronic means.