

Development of a Consumer Reported Outcome Measure for Personal Care Products : The Rationale

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ABSTRACT

Background: Cosmetic products are one of the fastest-growing segments of personal care products in the United States. One of the critical elements in the sales and growth of cosmetics is leveraging claims. Unlike pharmaceuticals in the US, claims in personal care products are usually not reviewed nor require regulatory approvals before products are sold in the US. However, regulatory agencies have no oversight of how the advertisement is presented to the consumers and have cited known companies and brands for promoting deceptive advertising and forcing costly market withdrawal, impacting the financial values of investors and customers' confidence alike.

Objectives: We conducted a literature search and a survey. The literature search was to identify the current methodologies available for substantiating the advertisement of personal care products (including cosmetics). The survey was conducted with regulatory professionals aiming to understand the use of the current methodologies.

Methods: The survey was developed and distributed to regulatory professionals in different capacities within the Cosmetic and Personal Care industry who had extensive experience constructing and substantiating advertising claims regulatory for cosmetic and personal care products. The questionnaire comprised 9 questions with socio-demographic characteristics and regulatory experience validating claims.

Results: We received 63 responses from 1354 forms sent from regulatory professionals validating advertising claims. The results show that 85 % of the respondents use the FDA guidance while the remaining 15 % use in-

house or other non-governmental guides. Moreover, 58 % use some Risk Benefit, while 42 % do not use it when evaluating claim substantiation.

Conclusion: Although the respondents qualifying the claims possess the experience and technical knowledge of Cosmetic and Personal Care Products, the presently available standards used in the US are not designed to validate the substantiation of advertising claims. Therefore, there is a need to develop a more robust methodology for the evaluation of the validation and substantiation of advertising claims. A technique of using personal experiences is already approved and used for pharmaceutical products known as Personal Reported Outcomes (PRO). Leveraging the PRO techniques can help develop a “consumer reported outcome measure” (CROM) tool for claim substantiation validation for the advertising of cosmetic and personal care products.

Keywords : Personal Reported Outcomes, CROM, FDA, FTC, Cosmetic products

I. INTRODUCTION

The sales of cosmetic products in the world are expected to grow from \$483B in 2020 to \$785B in 2025. (Figure 1).⁽¹⁾

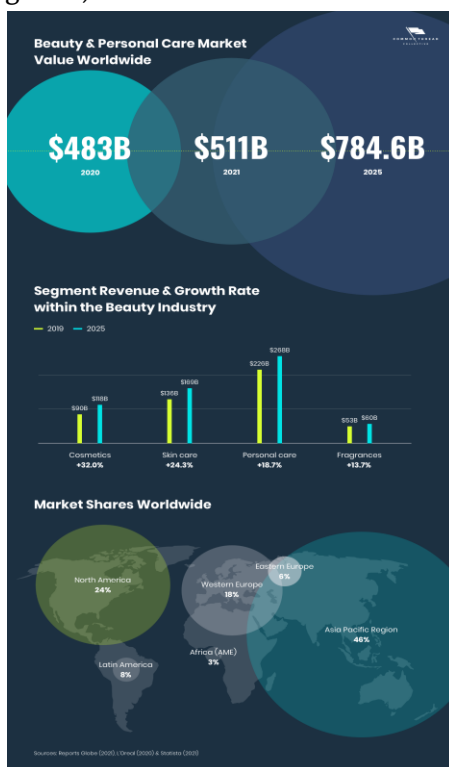


Figure 1. Global Cosmetic Sales from 2020 to 2025⁽¹⁾

The US is considered the most profitable cosmetics and personal care products market in the world⁽²⁾. One of the critical elements in the sales and growth of cosmetics is leveraging claims. Unlike pharmaceuticals in the US, claims in personal care products are usually not reviewed nor require regulatory approvals before products are sold in the US market when compared with markets such as the EU.⁽³⁾

Cosmetic products are becoming one of the fastest-growing global personal care categories, particularly in the US. A vital aspect of this growth is how these products are advertised. In the US, unlike the EU, the claims for cosmetic products do not require prior regulatory approval. One of the most used claims is personal testimonials. However, cosmetic products do not need prior regulatory approval, which allows manufacturers to place products in the US market with no restrictions when compared to prescription drugs. Regulatory agencies such as the Food Drug Administration (FDA) and Federal Trade Commission (FTC) have cited several companies such as L'Oréal⁽⁴⁾,

Sunday Riley Modern Skincare ⁽⁵⁾, and Nature City, LLC, ⁽⁶⁾ mentioning a few, for deceptive advertising. These citations resulted in the withdrawal of products and substantial economic loss, from fines to reimbursements. Moreover, these notifications have impacted these companies' financial values with investors and customers. Similar situations have been found outside the US. For example, the Advertising Standards Authority (ASA), the UK's independent advertising regulator across all media, has cited

companies such as L'Oréal for similar issues. ⁽⁷⁾ It has recently prompted issuing guidance on Beauty and Cosmetics: The use of production techniques on February 3, 2021. ⁽⁸⁾

1.1 Global Claim Substantiation for Cosmetic Products

The methods and protocols for claim substantiation are usually different worldwide, as shown between the EU and the US (Table 1).

Table 1. EU and US claim substantiation comparisons. ⁽⁹⁾

	European Union	United States
Enforcement	The European Commission sets cosmetic standards which are enforced by member country regulatory authorities.	The Food & Drug Administration and the Federal Trade Commission both have jurisdiction over cosmetic claims. Individual states have regulatory authority too.
Registration	Cosmetic products must be registered, and proof of claims must be filed before they go on the market.	Cosmetic products and ingredients do not need FDA registration, but they can be registered voluntarily. Claims are not filed with the agency.
Truthfulness	Claims must be truthful. i.e. if said to contain honey it must contain honey.	Companies must have competent and reliable evidence to substantiate any ingredient-related claims.
Evidence	Claims should be supported by verifiable evidence. Experimental studies should be reliable and reproducible.	To support performance claims companies, need both clinically and statistically significant data.

1.2 US claim substantiations for Cosmetic products

There are a few testing methodologies for cosmetics and personal care products to qualify claims in the US. However, none addresses how to measure and qualify testimonials. Although using testimonials is not limited to the Cosmetic and Personal Care industries, it is also used by pharmaceutical companies to enhance the advertising of prescription products. However, due to the scrutiny of regulatory agencies on prescription/pharmaceutical products, the message has to be heavily substantiated.

Cosmetic labels and their advertising do not require prior authorization approval for selling cosmetic products in the US.⁽¹⁰⁾ Although, it is not implied that regulators do not monitor the market for labelling misrepresentations on cosmetic products,⁽¹¹⁾ The body that should assume responsible for this function, in particular, is the Federal Trade Commission (FTC) under the auspices of the Fair Packaging and Labelling Act (FPLA).⁽¹²⁾ Because of this lack of clarity, personal care, and cosmetics manufacturers have, on several occasions, pushed the boundaries on the

claims used, resulting in being cited for promoting unsafe/unadulterated products in the US market.^(13,14,15) One of the key reasons for this anomaly is the lack of regulatory-approved methodologies for building / setting claims. Neither FDA nor FTC does indicate what to use when considering building suitable cosmetic products claims, unlike what it is recommended for prescription products. There is well-established guidance on the requirements on the substantiation required for prescription products. Usually, substantiations for pharmaceutical products require setting clinical trials involving dozens to several hundred individuals in controlled settings previously agreed with FDA.

Although no specific set is recommended for the Cosmetic / Personal Care Industries, the FTC has leveraged Truth in Advertising (TA)⁽¹⁶⁾ to gauge the claims' veracity. TA is a tool frequently used by the FTC to “gauge advertising claims that can affect consumers' health or their pocketbooks – claims about food, over-the-counter drugs, dietary supplements, alcohol, and tobacco and on conduct related to high-tech products and the Internet”.⁽¹⁷⁾ Both, the FDA and the FTC, use TA very often because of the use of testimonials by producers as well as retailers as they are considered major sales initiatives in the promotion of personal care and cosmetic products.⁽¹⁸⁾

The challenge arises, how can testimonials be used/leveraged with personal care products without infringing into the guidance set in Truth in Advertising (TA). Perhaps the answer is using Self-Reported Outcomes (SRO) methodologies by pharmaceutical companies where users' inputs are part of the label/advertising within reasonable boundaries. The SROs are part of the overall process known as Real World Evidence (RWE)⁽¹⁹⁾. According to the FDA website, “Real-world evidence is the clinical evidence regarding the usage and potential benefits, or risks of a medical product derived from analysis of Real-World Data (RWD). The RWE can be generated by different study designs or analyses, including but not limited to, randomized trials,

including large simple trials, pragmatic trials, and observational studies (prospective and/retrospective)”.⁽²⁰⁾ The use of RWE and RWD techniques are components of the SRO methodology. These techniques, referred to as “patient-reported outcome measures”, such as Dermatology Life Quality Index (DLQI)^(21,22), Cardiff Acne Disability Index (CADI)⁽²³⁾ and Hyperhidrosis Quality of Life instrument⁽²⁴⁾ among others, have been used in patients with skin diseases of whom some use personal skin care products. The FDA defines PRO as “instruments used to support claims in approved medical product labeling. A PRO instrument (i.e., a questionnaire plus the information and documentation that support its use) is a means to capture PRO data used to measure treatment benefit or risk in medical product clinical trials.” PROs have been quite successful in substantiating claims for oncological prescription products sold in the US as well as in other countries.⁽²⁵⁾ The aim of this study was therefore to explore the current methodologies available for personal care products (including cosmetics) substantiation based on consumer reported outcome measures.

II. METHODS AND MATERIAL

Following a literature review a questionnaire was also developed to identify current techniques (tools, questionnaires, surveys, and studies) available and used to determine the techniques for claim substantiation presently in use by industry and regulators alike. The development of the questionnaire for exploring the current environment of claim substantiation was based on the information obtained from the literature and subsequent brainstorming among the research team as well as content validation. This process led to the formatting of the final version of the Questionnaire.

Two online platforms were used for administration and data collection from the Questionnaire, namely

Qualtrics & Survey Monkey (Social Survey Tools). Content analysis using grounded theory was employed to analyse the collected qualitative data.

III. RESULTS

3.1 Literature Review

The literature review identified several protocols and methodologies for claim substantiation used for promotion and marketing of personal care products in the US as well as in other countries. These were as follows:

- **ASTM E-1958-20 Standard Guide for Sensory Claim Substantiation** ⁽²⁶⁾

The ASTM E 1958 document was created to provide a comprehensive approach (guide) to validating sensory based advertising claims.

- **A Guide to United States Cosmetic Products Compliance Requirements - NISTIR 8178** ⁽²⁷⁾

This guide addresses the compliance requirements for basic cosmetics and soap.

- **Fair Packaging & Labelling Act – 16CFR500** ⁽²⁸⁾

The Fair Packaging and Labeling Act (FPLA), implemented in 1967, empowers the Federal Trade Commission and the Food and Drug Administration to promote regulations requiring that all "consumer commodities" be labeled to disclose net contents, identity of commodity, and name and place of business of the product's manufacturer, packer, or distributor. The Act also issues additional regulations where necessary to prevent consumer deception.

Colipa's Guidelines for Cosmetic Product Claim Substantiation ⁽²⁹⁾

Cosmetic product claims are subject to a framework of regulation and self-regulation that is comprehensive and ensures a high level of consumer protection from misleading claims. This framework combines horizontal (i.e., applying to all advertising and

commercial practices) and cosmetic-specific legislation with self-regulation.

COSMETIC PRODUCT CLAIMS – EC -Regulation 655/2013 ⁽³⁰⁾

EU Regulation No 655/2013 lays down standard criteria for substantiating claims about cosmetic and personal care products. The regulation applies to any cosmetic and personal care product claim, irrespective of the medium or type of marketing tool used, the product functions claimed, and the target audience.

FDA Cosmetics Labeling Guide ⁽³¹⁾

The FDA does not approve cosmetic labeling before cosmetic and personal care products are introduced in the US market.

Moreover, the FDA does not have a list of approved or accepted claims for cosmetics. However, the FDA acknowledges that cosmetic labeling has limits. The information provided must be truthful and not misleading. More importantly, a product marketed with claims to treat or prevent a disease or affect the structure or function of the body—including the skin—is considered a drug by the law, and it must meet the requirements for drugs, even if they affect the appearance.

ISO 20784:2021 – Guidance on Substantiation for Sensory and Consumer Claims ⁽³²⁾

This document guides on substantiating sensory claims on food and non-food products and their packaging for advertising consumer-packaged goods. It differentiates sensory claims from other types of claims. It provides classification and examples of the different types of sensory claims. It highlights special issues associated with testing to substantiate sensory. It includes case studies and references to help the user design the testing. However, it does not apply to the Specific or detailed requirements for different test methods to support sensory claims.

CTPA Tool for Claim Substantiation⁽³³⁾

The UK Cosmetic Toiletry and Perfumery Association (CTPA) has the CTPA Claim Substantiation Tool. The Tool takes into account all the factors that have to be considered when building robust claim substantiation. It uses a column step-by-step approach, where all conditions should not be isolated. There must be a clear connection between the rationale, the evidence, and each of the following factors: the wording and context of the claim and how the consumer perceives or understands the claim. Companies can:

Use the Tool for each claim made on a specific product, whether they are featured on product labels or online advertising, among others.

- Use the Tool to guide the thought process to ensure claims are robustly substantiated.
- Use the Tool to ensure all critical factors are taken into consideration for claim substantiation, including that the claim context must be made for easy understanding of the reasonably well-informed, reasonably observant, and circumspect consumer.
- Use the Tool to guide the compilation of the claim support dossier that must be part of the Product Information File (PIF) per Article 11 of the UK Cosmetics Regulation.

This tool is not intended to introduce mandatory requirements or to replace individual company practices. Companies with an internal template in place to support the claim substantiation process may, however, use the CTPA Claim Substantiation Tool to ensure that these include all relevant considerations as per industry best practices.

EC1223-2009⁽³⁴⁾

Regulation (EC) N° 1223/2009 on cosmetic products is the main regulatory framework for finished cosmetic products when

placed on the EU market. It strengthens the safety of cosmetic products and streamlines the framework for all operators in the sector.

3.2 The Questionnaire Technique

The study was conducted with regulatory professionals working in different capacities within the cosmetic and personal care industries. The study was designed to be conducted online and provide complementary evidence to the learnings from the literature review. One thousand three hundred fifty-four professionals involved in cosmetics, such as formulation, quality, and marketing, among others, were contacted, and 63 completed the questionnaire.

The questionnaire responses are divided into two sections:

Section 1, Participants Socio-demographics characteristics

Section 2. Participants regulatory experience validating claims

3.2.1 Section 1 - Socio-demographic characteristics of the study participants

The socio-demographic profile and professional background of the participants are summarised in Table 1. The results showed that

- 40 % of are 60 years or older.
- 65 % are males, 32 % female and 3 % binary.
- 65 % have a Post Graduate (Masters, PhD, Law and Medical Degrees), 27 % are college graduates and 8 % completed High School.
- 76 % are employed, 15 % retired but still involved and 8 % unemployed.
- 31 % are employed in industry, 28 % in mixed operations, 17 % in academia and 2 % in government.
- 31 % spend their time on Claim Substantiation validation.
- 36 % have been involved in the field between 10 to 20 years while 32 % have been involved between 20 to 30 years.

IV. DISCUSSION

The literature review found several procedures, either in the US or the EU, presently in use to validate advertising claims from a sensory perspective. These procedures specify the testing protocols needed to substantiate the desired claims. Some, such as the US Fair Packaging & Labelling Act, note that all statements must be truthful and not misleading according to the Truth in Advertising Laws set by the US Federal Trade Commission (35). The same approach, not to provide misleading statements when validating claims, is part of EC1223-2009. In others, such as EU Colipa, where the claims must be part of a combination of existing regulations and self-regulations of the organization's marketing group, the substantiation is thorough, ensuring consumer protection from any misleading claims. Some, such as ISO 20784:2021, provide a classification of the different sensory claims the user can and cannot substantiate based on the type of products being sold. While others, like the UK CTPA tool, will instruct the user to consider all the factors when building robust claim substantiation. The survey results show that most % of respondents, 85, will use guidance issued by the FDA, while the remaining will use internal guidance from other regulatory agencies. The most noticeable part is that 58 % of the respondents use some Risk Criteria when evaluating claim substantiation. The respondents did not disclose the type of Risk Criteria methodology they used. The reason for not disclosing can be due to their non-disclosure agreements signed with their employers and clients alike. Although a limited number of participants completed the survey, it can be considered representative of the regulatory professionals in the Cosmetic and Personal Care industries. The results show that although the individuals involved in qualifying the claims possess the experience and technical knowledge of Cosmetic and Personal Care Products, the presently available

standards used in the US need to be designed to validate the substantiation of advertising claims. Moreover, since the claims do not require FDA approval prior to launching any cosmetic and personal care product in the market, the manufacturer is solely responsible for the accuracy of the advertised claims with the potential liability of legal action from regulatory authorities such as the FDA and FTC and Non-Governmental Organizations (NGO) raising concerns about the safety and truthfulness of the products sold. Therefore, there is a need to develop a robust methodology validating claim substantiation for the advertising of Cosmetic and Personal Care products when using testimonials.

V. CONCLUSION

Although the study identifies several methods, none are applicable nor valuable for the validation of advertising claims. Moreover, there is no particular guidance from the FDA or the FTC on substantiating consumers' inputs for the validation of advertising of personal care products. Because the present methodologies only address the sensorial aspects of personal care products, those regulatory professionals working in the Cosmetic industry must rely on several procedures to confirm the validity of the proposed desired claims. Moreover, the review shows the need to develop similar techniques as a PRO for Consumer and Personal Care Products since the present guidance is not as robust and comprehensive as those used for prescription drug products in the US. Therefore, developing a Consumer Research Outcome Measurements (CROM) tool could become the most promising substantiation technique for validating and helping regulatory professionals select the most robust advertising claims for cosmetic and personal care products sold in the US. Therefore, the following step in the research is conducting surveys to identify the critical codes required for the CROM tool design similarly, when developing PROs (36, 37, 38, 39, and 40). Then, after the codes have been identified, we

will use these codes to develop and test CROM tool prototypes before finalizing the methodology. The final CROM tool methodology will be shared with the FDA for evaluation.

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Ethics declarations

1) **Funding**

The authors received no external financial support for the research, authorship or publication of this article.

2) **Conflicts of Interest/Competing Interests**

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

3) **Ethics Approval**

Ethics approval was not required as described in Sect. [2.2](#) of this article.

4) **Consent to Participate**

Participant consent to participate in the survey was obtained as described in Sect. [2.2](#) of this article.

5) **Consent for Publication**

Not applicable.

6) **Availability of Data and Material**

Survey data collection and publicly available data from the TGA website was used to support the information in this article.

7) **Code Availability**

Not applicable.

8) **Author's Contributions**

AY wrote the manuscript. OC, GS and JL reviewed and edited the manuscript. AY and OC designed research, AY performed research and analysed data. OC, GS and JL reviewed data and data analysis. All

authors have read and approve the final submitted manuscript and agree to be accountable for the work.

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