

Regulatory Insights: Around-the-world overview

Nutri-Beauty: Mastering the Market

Angela Diesch, Esq.

Blog <http://www.CosmeticsAndTheLaw.com>

www.DieschLawGroup.com

angela@DieschLawGroup.com

O: (916) 740-6470

C: (530) 400-4369



Agenda



- US: FTC Influencer Rules
- EU: Free From Claims

FTC GUIDELINES FOR INFLUENCERS, ENDORSERS, & TESTIMONIALS

INTERNET & SOCIAL MEDIA

- A firm is responsible for product promotional communications on websites that are:
 - owned,
 - controlled,
 - created,
 - influenced by,
 - operated by, or
 - on behalf of, the firm.

Includes 3rd party site if any control or influence

→even if limited in scope:
•content collaboration •editorial or •review privileges



IS IT THE FIRM'S CONTENT?

Responsibility run with content generated by:

- an employee or agent to promote the firm's product
- sales representative posts comments about the firm's product on an independent third-party site
- blogger paid by a firm maintains a blog about the firm's product

Passive Posting:

- Re-Tweet
- Favorite
- Likes

...constitute communication and are subject to FDA communications regulations.

USER GENERATED CONTENT (UGC)

- NOT responsible for UGC IF truly independent of the firm → is not produced on behalf of nor prompted by
- UGC on firm-owned or firm-controlled venues NOT generally viewed as promotional content on behalf firm IF no affiliation & no influence
- BUT what out for ratification!

UGC ON YOUR PLATFORM...

- May not edit the UGC content.

Again –watch out for ratification–

- Allowing a customer review on firm website or social media site (e.g., Facebook page, IG, Twitter), a company implicitly adopts the statement and is considered to make the claim itself.
 - Claim must be able to substantiate underlying claim
 - Claim must be appropriate for product category (e.g., no drug claims for cosmetic products)
- STATE T&Cs on Website

EXPERT ENDORSERS

- Appropriate qualifications as an expert
- Disclose personal, financial, or similar connections
- Examination or testing would be generally recognized in the field as sufficient to support the endorsement
- Reasonable basis for the opinion
- Evaluation based on actual exercise of expertise relevant to features or characteristics within her expertise
 - Relevant to an ordinary consumer's use of or experience with the product and
 - Available to the ordinary consumer.

Testimonials

- Testimonials Can Be Deceptive:
 - Endorser may not have experienced the reported result.
 - Experience attributable to other factors → diet, exercise, lifestyle changes, climate, time of year.
 - If presented as typical and ordinary result → likely deceptive without an indication of the more modest results that the typical user would experience.

FOLLOW THE CONTENT

Disclosures Need to Follow Content

Share sample videos

“FREE FROM” CLAIMS: US & EU

EU – FREE FROM GUIDANCE

- First issued in 2017 and updated in 2019
- Guidance document – not regulation
- Best practices versus a requirement?
 - Depends on the member state's interpretation
- Six Common Criteria:
 - Legal compliance
 - Truthfulness
 - Evidential support
 - Honesty
 - Fairness
 - Informed decision-making

LEGAL COMPLIANCE

- Claims that product is authorized or approved by a competent authority within the Union since a cosmetic product is allowed on the Union market without any governmental approval.

"this product complies with provisions of the EU cosmetics legislation"

- Claims which convey the idea that a product has a specific benefit when this benefit is mere compliance with minimum legal requirements

"skin care product does not contain hydroquinone"

TRUTHFULNESS

- General presentation nor individual claims made for the product should NOT be based on false or irrelevant information

'silicone-free' → if contain silicone

'48-hour hydration' → evidence only supports a shorter period of hydration.

- If a product claims that it contains a specific ingredient, the ingredient should be deliberately present.

'contains honey' → must actually contain honey, and not only honey flavor

TRUTHFULNESS

- Ingredient claims referring to the properties of a specific ingredient should not imply that the finished product has the same properties when it does not.

“contains moisturising aloe vera” or prominently picturing aloe vera → no moisturizing effect.

- Marketing communications should not imply that expressions of opinions are verified claims unless the opinion reflects verifiable evidence.

EVIDENTIAL SUPPORT

- Claims, whether explicit or implicit, supported by adequate and verifiable evidence regardless of the types of evidential support used to substantiate them, including where appropriate expert assessments
- Marketing communications should not imply that expressions of opinions are verified claims unless the opinion reflects verifiable evidence.

EVIDENTIAL SUPPORT

- The responsible person:
 - Determines the appropriate and sufficient methodology to be used for claim substantiation.
 - Determines the appropriate supporting evidence. Such evidence can be of different kinds and forms and should be justified where necessary in the PIF
 - Should have appropriate and adequate scientific evidence to substantiate the claim made whether explicit or implied.
 - May consult an expert who will provide the appropriate support.
 - Should ensure the evidential support is still applicable when the formulation of the product changes.

EVIDENTIAL SUPPORT

- Studies relevant to the product and claimed benefit, & well-designed, well-conducted methodologies (valid, reliable and reproducible) and respect ethical considerations.
- Level of evidence or substantiation consistent with type of claim being made, especially where lack of efficacy may cause a safety problem, e.g. sun protection claims.
- Puffery (hyperbole) or abstract nature do not require substantiation.
- Ingredient properties to the finished product → adequate and verifiable evidence, e.g., demonstrating the presence of the ingredient at an effective concentration.
- Assessment of a claim → weight of evidence of all studies, data and information available depending on the nature of the claim and the prevailing general knowledge by the end users.

HONESTY

- Presentations of a product's performance should not go beyond the available supporting evidence.
- Claims should not attribute to the product concerned specific (i.e. unique) characteristics if similar products possess the same characteristics.
- If the action of a product is linked to specific conditions such as use in association with other products, this should be clearly stated.

FAIRNESS

- Claims for cosmetic products should be objective and should not denigrate the competitors, nor should they denigrate ingredients legally used.

“contrary to product X, this product does not contain ingredient Y which is known to be irritating”

“Well tolerated as it does not contain mineral oils”

“Low in allergens because without preservatives”

- Claims for cosmetic products should not create confusion with the product of a competitor.

Comparing the effectiveness against wetness of an anti-perspirant against a deodorant → not fair, as the two are different products with different functions.

INFORMED DECISION-MAKING

- Claims should be clear and understandable to the average end user.
- Claims are an integral part of products and should contain information allowing the average end user to make an informed choice.
- Take into account capacity of the target audience (population of relevant Member States or segments of the population, e.g. consumers of different age and gender, or professionals) to comprehend the communication.
 - clear, precise, relevant and understandable by the target.

U.S. “FREE-OF” GUIDANCE

- For a product that contains some amount of a substance if:
 - NO more than trace amounts or background levels;
 - The amount present doesn't cause harm that consumers typically associate with the substance; and
 - The substance wasn't added intentionally
- Deceptive IF free of one substance but includes another that poses a similar environmental risk.
- May be deceptive if substance never has been associated with that product category
 - e.g., claiming BPA free on a glass bottle, or claiming an anhydrous formulation (e.g., lip balm) is preservative free

Questions ??



Thank You!