LIFE SCIENCES BOOTCAMP SERIES: CONSUMER PROTECTION AND FDA

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INTRODUCTION

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OVERVIEW

- The FDA and the FTC
- Advertising Principles
- Social Media
- Customer Reviews

THE FDA AND THE FTC

EVOLVING REGULATORY ENVIRONMENT

Cheerios' Health Claims Break Rules, FDA Says

By Jennifer Corbett Dooren
Updated May 13, 2009 11:59 pm ET

PRINT TEXT

The Food and Drug Administration slapped General Mills Inc. GIS -2.37% ▼ with a warning over its Cheerios cereal, saying the box's claims about heart benefits contain "serious violations" of federal law.

In a May 5 warning letter sent to the company and posted on the FDA's Web site Tuesday, the agency said statements that the product is "clinically proven to help lower cholesterol" make the product a drug under federal law.

FTC Holds Workshop on "Dark Patterns" and Seeks Public Comments

By Leonard L. Gordon, Shahin O. Rothermel and Megan K. Hynes on May 03, 2021 11:55 am

On April 29, 2021, the Federal Trade Commission ("FTC") held a virtual workshop, Bringing Dark Patterns to Light, which discussed the use of "dark patterns," how they impact consumers, and ways the FTC can combat these methods. What are dark patterns? The FTC has defined "dark patterns" as website design features or interfaces which are... Continue Reading

FTC Sends Tenth Round of Warning Letters Over COVID-19 Claims to Marketers, Putting Social Media and Other Platforms ...

The Federal Trade Commission announced that it sent out thirty more warning letters to marketers, directing them to s...
Jeff Greenbaum - 01/05/2021

CooperSurgical Cited for IUD's DTC TV Ad

August 1, 2019

The FDA slapped Connecticut devicemaker CooperSurgical with an untitled letter over a direct-to-consumer TV ad for its ParaGard T380A copper contraceptive, an intrauterine device.

FDA warns makers of Purell to stop advertising that it can prevent Ebola, the flu and more

The warning comes at a time when the new coronavirus fuels worldwide anxiety.

U.S. FOOD AND DRUG ADMINISTRATION OVERVIEW

- Protects the public health by ensuring the **safety, efficacy, and security** of **human and veterinary drugs, biologics** products, and **medical devices**, and by ensuring the safety of the U.S. **food** supply, **cosmetics**, and **electronic products that emit radiation**
- Regulates the **manufacture, marketing, and distribution** of **tobacco** products to protect the public and reduce tobacco use by minors
- **FDA-regulated products account for about 20-25 cents of every dollar spent by U.S. consumers!**

FEDERAL TRADE COMMISSION'S BUREAU OF CONSUMER PROTECTION OVERVIEW

- The **Bureau of Consumer Protection**'s mandate is to protect consumers against unfair, deceptive or fraudulent practices.
- The Bureau enforces a variety of consumer protection laws enacted by Congress, as well as trade regulation rules issued by the Commission.
- Its actions include individual company and industry-wide investigations, administrative and federal court litigation, rulemaking proceedings, and consumer and business education.
- Covers: Privacy; Advertising; Marketing; Labeling; Reviews; Endorsements and Social Media

FDA / FTC WARNING LETTERS

FTC and FDA Send Warning Letters to Companies Selling Dietary Supplements Claiming to Treat Alzheimer's Disease and Remediate or Cure Other Serious Illnesses Such as Parkinson's, Heart Disease, and Cancer

February 11, 2019

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FOR YOUR INFORMATION

TAGS: Food and Drug Administration (FDA) | Bureau of Cons
Advertising and Marketing | Health Claims | Health

As part of its ongoing efforts to ensure that dietary supplements
truthfully, and that efficacy claims made for such products are su
evidence, the Federal Trade Commission has joined the U.S. Fo
warning letters to companies based in Florida, South Carolina, a

As detailed in the letters sent to Gold Crown Natural Products, T
Commission has reviewed the companies' advertisements and b
false or unsubstantiated health claims. Specifically, the FTC is w
Alzheimer's and remediate or cure other serious illnesses includ

For example, the letter to Gold Crown Natural Products questior
three other supplements. Among others, the FTC questions the
this and it is proved that melatonin supplements are used to cur

The letter sent to TEK Naturals identifies health claims made for
advertised as "[c]linically shown to help diseases of the brain su
products claimed to treat or prevent some forms of cancer, Park
stones, among others.

FTC, FDA Send Warning Letters to Seven Companies about Unsupported Claims that Products Can Treat or Prevent Coronavirus

March 9, 2020

Commission continues efforts to protect consumers from deceptive advertising

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FOR RELEASE

TAGS: Coronavirus (COVID-19) | Food and Drug Administration (FDA) | Health Care |

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FDA NEWS RELEASE

FDA, FTC warn company marketing unapproved cannabidiol products with unsubstantiated claims to treat teething and ear pain in infants, autism, ADHD, Parkinson's and Alzheimer's disease

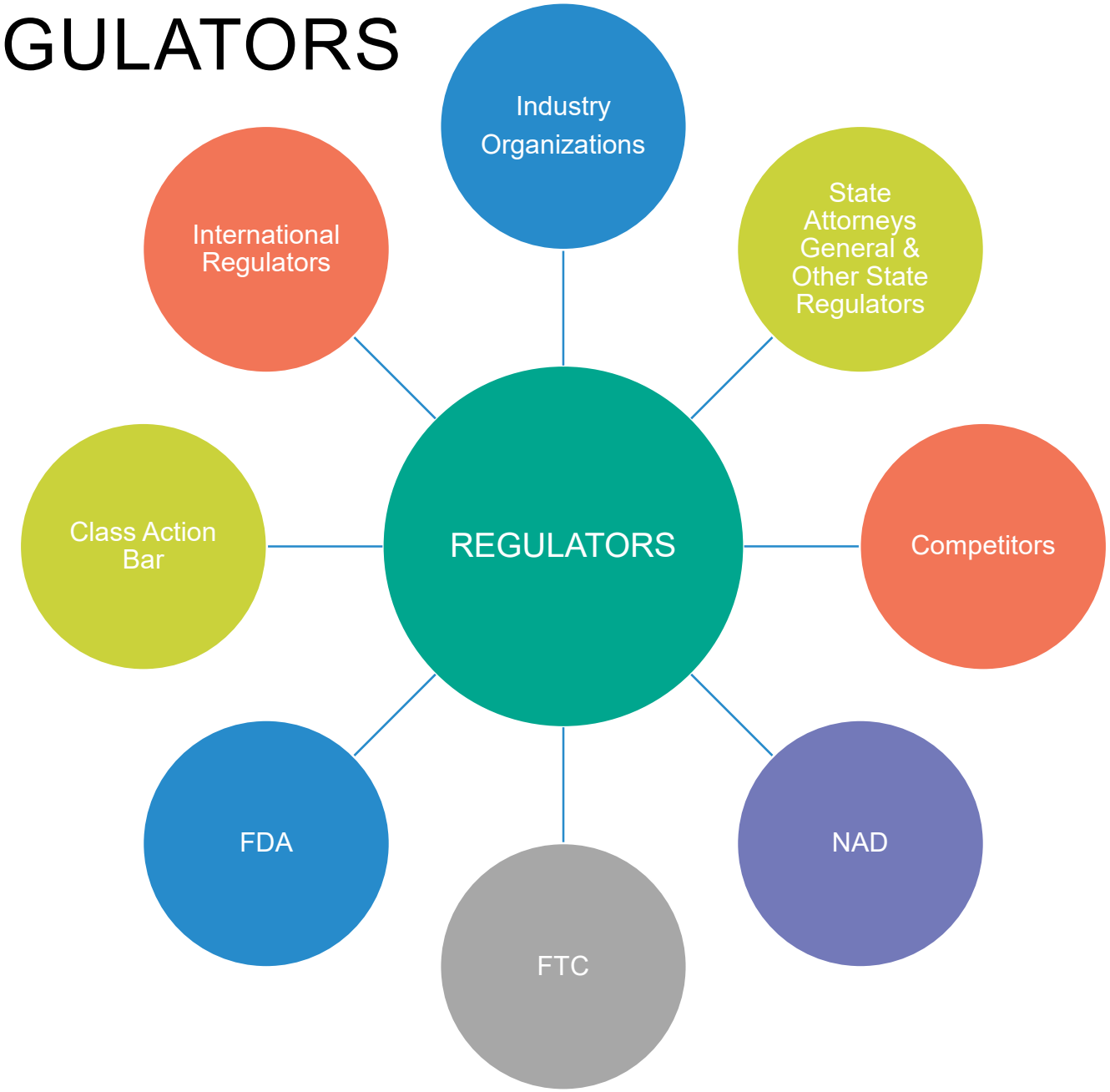
FDA is also working quickly to evaluate regulatory policies related to cannabis and cannabis-derived ingredients like CBD

ADVERTISING PRINCIPLES

WHO REGULATES ADVERTISING AND PROMOTION?

- The Federal Food, Drug, and Cosmetic Act (FDCA) gives **FDA** authority to regulate:
  - The marketing or distribution of FDA-regulated products in **interstate commerce** (e.g., mail, wire, and other mechanisms of interstate commerce)
    - Prohibits the sale and distribution of adulterated and misbranded devices
  - The content of **labeling** for all FDA-regulated products and **advertising** for Rx drugs, restricted devices and tobacco
    - FDA authorized to regulate advertising for restricted devices and exempts such devices from sections 12-15 of the FTC Act
    - FDA may designate a device as restricted through regulations, performance standards or as a condition of approval
- The Federal Trade Commission Act (FTC Act) gives **FTC** authority to regulate:
  - Advertising of over-the-counter (OTC) drugs, non-restricted devices, food, cosmetics, and other FDA-regulated products
  - Advertising of other consumer-directed products and services
  - B2B promotional activity
- The FTC Act and regulations prohibit unfair and deceptive trade practices
  - *E.g.*, statements, omissions of material facts, practices that are likely to mislead consumers

OTHER REGULATORS



BASIC AD/PROMO REQUIREMENTS

- Regulators focus on the "**net impression**" of the entire item or program (context, surrounding content, marketer's intent)
- **Claims** (express, implied, comparative) must be **substantiated**
- Statements must be **truthful and non-misleading**
- Cannot be **deceptive** (must disclose risks, limitations or other "material" facts and can't present facts in a false or deceptive light)

WHO IS THE “REASONABLE CONSUMER”?

- FDA and FTC review advertisements from the point of view of a “reasonable consumer.”
  - A consumer acting reasonably in the circumstances
  - This standard does not preclude multiple interpretations of a claim
- If the promotion is directed primarily to a particular group, the agencies examine reasonableness from the perspective of that group.
  - Due to their training and experience, healthcare providers (HCPs) are believed to have a level of knowledge related to scientific concepts and medical conditions and products that lay consumers do not possess
  - However, HCPs are subject to the same cognitive biases and processing limitations as non-experts (i.e., signals and risk framing)

NET IMPRESSION

- FDA and FTC evaluate the “net impression” conveyed in each promotional piece
- A promotional communication that conveys a deceptive net impression of the product could be misleading, even if specific individual claims or presentations are not misleading
  - Does the piece as a whole convey an accurate and non-misleading impression of the benefits and risks of the promoted product?
  - Agencies will look beyond specific risk-related statements or individual claims
- The “net impression” is “the message communicated by all elements of the piece as a whole,” including:
  - the context
  - words, phrases, and pictures
  - signals and other method of conveyance (e.g., formatting, tone, amount of information)
  - risk framing (e.g., “like all treatment options, Device X…”)

WHAT IS “FALSE OR MISLEADING”

- Claims may be false or misleading if they:
  - Do not include appropriate content and context of information
  - Suggest that non-clinical data has clinical significance when no such clinical significance has been demonstrated
  - Misrepresent literature, data, or quotes from other sources
  - Use headline, pictures, or graphic matter in a misleading manner
  - Suggest a device is safer or more effective than has been demonstrated

WHAT IS “DECEPTIVE”?

- Material omissions can be deceptive; claims can be truthful, but also misleading
- Whether the claim is “material” – that is, important to a consumer’s decision to buy or use the product or service
- Examples of material claims are representations about a product or service’s performance, features, safety, price, effectiveness or the consequences that may result from the use of the device as recommended

CLAIMS SUBSTANTIATION

- It is a deceptive practice to make **unsubstantiated claims** about a product or service
  - An advertiser must have a reasonable basis for all express and implied claims about the product or service before disseminating the claims
- If an advertiser makes an express or implied statement about the amount of support it has for a claim (*e.g.*, "studies show"), it must have the **amount and type of substantiation claimed**
  - The exact amount and type of substantiation required depends on several factors, including the product or service, the claim being made, the consequences of a false or misleading claim (*e.g.,* risks to users), the benefits of a truthful claim, the cost of substantiating the claim, and the substantiation that experts in the field would consider reasonable

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

1. Labeling cannot be "**false or misleading** in any particular"
2. Labeling for certain products must contain "**adequate directions for use**" and information required by regulations
3. Advertising cannot be false, misleading, or **deceptive** and must contain information required by applicable regulations for the advertised product
4. Statements and claims regarding the product's "**intended use**" must be:
   - within the scope of (i) approved marketing application, (ii) FDA-approved product labeling, and (iii) FDA regulations
   - Product claims must be "**on-label**" or "**consistent with the label**"
   - **Substantiated** (*e.g.*, by "competent and reliable scientific evidence" or standard for FDA clearance or approval)

FEDERAL TRADE COMMISSION (FTC)

- Many similarities to the FDA – statements must be truthful and accurate, and must have sufficient substantiation
- The FTC will look at express claims and implied claims
- Health and safety claims receive increased scrutiny, as do statements directed at children or the elderly
- FTC accepts referrals from NAD, division of the Better Business Bureau tasked with investigating truth and accuracy in advertising and deciding competitor advertising disputes
- Terms and conditions, material connections, contents, any claims must all be adequately and properly disclosed

SOCIAL MEDIA

THIRD-PARTY MEDIA CONTENT

- Third-party media content and “native advertising” are growing in popularity as a way to connect with customers and leverage third-party messaging to support product messages
- Because these trends are evolving, current marketing and promotion laws do not specifically address the full range of these activities
- Use of or support for third-party media content can trigger FDA and FTC advertising and promotion laws
- It is important to develop guiding principles for these activities that address and minimize legal and compliance risks

THIRD-PARTY CONTENT: DISCLOSURES

- Material connections must be adequately disclosed on all endorsements, including statements in social media
  - Material Connection: any financial, employment, personal, or family relationship with a brand, including receiving free product or anything of value
  - Adequate Disclosure: clear and conspicuous, “can’t be missed”
    - #ad before clicking more, displayed in the first 2-3 lines, standing alone
- Be aware that social media posts can trigger other regulations and requirements, like sweepstakes and lotteries
- Include appropriate provisions in agreements with influencers and celebrities

THIRD-PARTY CONTENT: FTC IMPLICATIONS

- Governed by the FTC's *Endorsement Guides* (16 C.F.R. Part 255)
  - Endorsements **cannot convey express or implied claims that would be deceptive** if advertiser made them directly
  - Must have **adequate substantiation** for all claims (express or implicit) made through endorsements
  - Endorsements must reflect the **honest opinions, findings, beliefs, or experience** of the endorser
  - If the ad represents that the endorser used the product, they must have been a **bona fide user**
  - Must **disclose material connections** with the endorser

THIRD-PARTY CONTENT: FDA IMPLICATIONS

Third-party content implicates advertising laws when it:

- Discusses or describes medical products by name, brand, or type
- Makes implied or express claims about clinical or economic outcomes associated with medical products
- Uses customer data, program data, clinical guidelines, or published research to describe medical product benefits or outcomes
- Includes patient or HCP testimonials and individual use cases that discuss experiences with the product or a competitor product or brand
- Is adopted or used by the medical product manufacturer to promote the company's product or further its brand or selling messages

THIRD-PARTY CONTENT: FDA IMPLICATIONS CONT'D

- Same evidentiary standards as if manufacturer is making the claim directly
- Patient or healthcare provider testimonials and individual case studies may be an accurate reflection of one patients' experience, but that alone is unlikely to fully substantiate the claim
- Treatment response must be reflective of results of clinical trials
- "Individual results may vary" does not mitigate misleading presentation

THIRD-PARTY TESTIMONIALS AND ENDORSEMENTS

- “The social media post is false or misleading in that it presents efficacy claims for DICLEGIS, but [it] **fails to communicate any risk information** associated with its use and it omits material facts.”

- Firm responsible for promotion both on sites that it owns or controls **and third-party sites if the firm "exerts influence over a site in any particular, even if the influence is limited in scope," such as "collaborat[ing] on or ha[ving] editorial, preview, or review privilege over the content provided.”**

TEAMI CASE

FTC's Teami case: Spilling the tea about influencers and advertisers

By: Lesley Fair | Mar 6, 2020 11:22AM

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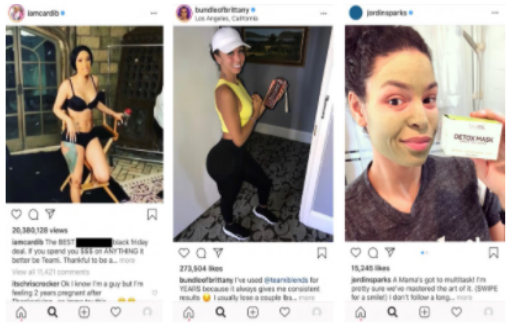
TAGS: Bureau of Consumer Protection | Consumer Protection | Advertising and Marketing | Endorsements, Influencers, and Reviews | Health Claims | Online Advertising and Marketing

The "what" of the FTC's settlement with Teami, LLC, shouldn't come as a surprise. The complaint alleges the defendants took in more than $15 million by deceptively claiming their array of teas could cause rapid and substantial weight loss, "fight against cancerous cells," decrease migraines, unclog arteries, and prevent colds and flu. What's different is the "how." The defendants advertised primarily through a massive social media campaign. Also notable is the "who" – a roster of celebrities and influencers, some of whom have now been sent warning letters reminding them of their legal obligation to disclose their connections to the products they promote.

Florida-based Teami and co-owners Adi Halevy and Yogev Malul sell Teami-branded teas, including the Teami 30 Day Detox Pack, and Teami-branded skincare products. The defendants didn't just convey claims on their website. They paid celebrities and other social media influencers with millions of followers to endorse their products on Instagram. The complaint cites examples of Teami making allegedly misleading weight loss claims for the 30 Day Detox Pack through its paid influencers' Instagram posts.

The FTC also alleges that Instagram posts by well-known entertainers and other influencers failed to disclose adequately that the defendants had paid them to endorse Teami products. Cited in the complaint are examples from recording artists Cardi B and Jordin Sparks; TV personalities Adrienne Bailon, Jenicka Lopez, Leyla Milani-Khoshbin, Darnell Nicole, and Alexa PenaVega; and influencers Katya Elise Henry, Princess Mae, and Brittany Renner. FTC staff has sent warning letters to those ten people.



- FTC sent warning letter stating that consumers viewing posts on Instagram typically see only the first few lines unless they click "more" and thus **endorsers should include any material connection above the "more" link**
- Teami responded by implementing a social media policy given to influencers or included in their contracts directing them to include effective disclosures
- FTC alleged the new policy did not result in effective disclosures
- **$15.2 million settlement** and requirement to maintain system to monitor and review how endorsers disclose material connections

CUSTOMER REVIEWS

CUSTOMER REVIEWS

- Section 5 of the FTC Act prohibits unfair and deceptive acts and practices. When it comes to reviews this means:
  - Negative reviews cannot be suppressed
  - Negative reviews cannot be hidden – reviews should be displayed by date, not star rating
  - Incentives for reviews must be disclosed – such as being entered in a sweepstakes
  - Material connections between the reviewer and the reviewed product must be disclosed – such as an employee or owner of the company, receipt of free product
  - Review gating is prohibited

CUSTOMER REVIEWS CONT'D

- The Consumer Review Fairness Act makes it illegal for companies to include standardized provisions that threaten or penalize people for posting honest reviews.
- The Act makes it illegal for a company to use a contract provision that:
  - bars or restricts the ability of a person who is a party to that contract to review a company's products, services, or conduct;
  - imposes a penalty or fee against someone who gives a review; or
  - requires people to give up their intellectual property rights in the content of their reviews.
- The law doesn't apply to employment contracts, independent contractors.

CUSTOMER REVIEWS CONT'D

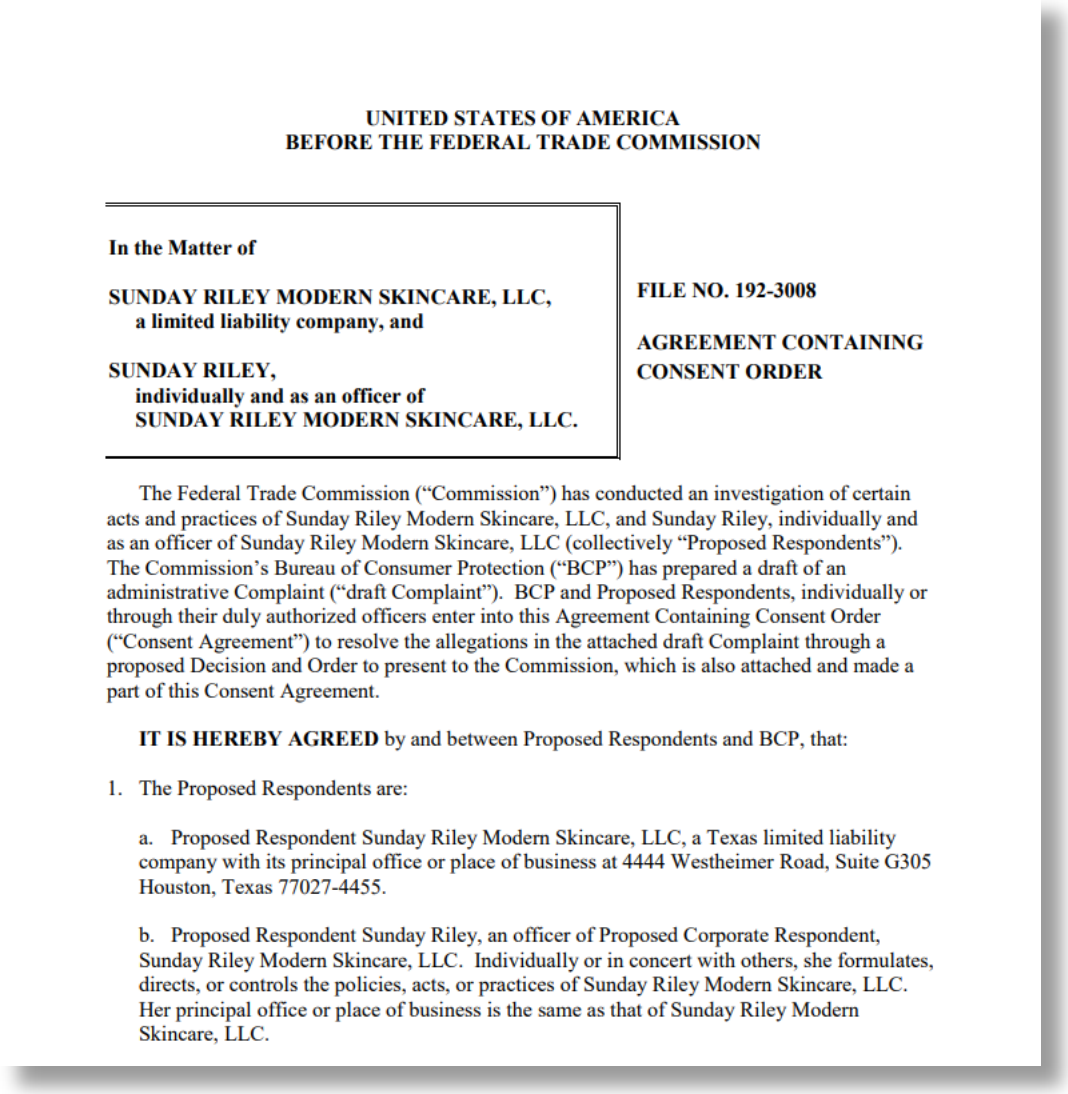
- However, as a Company, you do have some rights with regard to reviews.
- You can remove reviews that:
  - Contain confidential or private information
  - Are libelous, harassing, abusive, obscene, vulgar, sexually explicit, or are inappropriate with respect to race, gender, sexuality, ethnicity, or other intrinsic characteristics;
  - Are unrelated to the company's products or services; or
  - Are clearly false or misleading

CUSTOMER REVIEWS CONT'D

- FDA has largely adopted the FTC's Endorsement Guides
- FDA Guidance on Third Party User-Generated Content, Reprints and Correcting Third Party Misinformation
  - Manufacturers are responsible for promotion of third-party content (*e.g.*, articles, documentaries) if they have *any* control or influence, *even if* limited in scope
  - Independence test – Manufacturer not held responsible for third-party content that is "truly independent" and not adopted by Manufacturer

FTC - RILEY

- FTC alleged Sunday Riley managers—including CEO Riley—posted fake reviews of products on Sephora website using fake accounts to hide their identity
- Charged with (1) making false or misleading claims that the fake reviews reflected the opinions of ordinary users, and (2) deceptively failing to disclose that Sunday Riley employees wrote the reviews
- Settled with administrative consent order, which
  - Prohibits Sunday Riley and Ms. Riley from making any representation about any consumer or other product endorser without clearly and conspicuously disclosing any unexpected material connection between the endorser and any respondent or entity affiliated with the product
  - Requires that such disclosures be made in close proximity to the product review or endorsement
  - Requires the respondents to instruct their employees and agents about their responsibilities to clearly and conspicuously disclose their connections to Sunday Riley in any endorsement



UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of

SUNDAY RILEY MODERN SKINCARE, LLC,
a limited liability company, and

SUNDAY RILEY,
individually and as an officer of
SUNDAY RILEY MODERN SKINCARE, LLC.

FILE NO. 192-3008

AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission ("Commission") has conducted an investigation of certain acts and practices of Sunday Riley Modern Skincare, LLC, and Sunday Riley, individually and as an officer of Sunday Riley Modern Skincare, LLC (collectively "Proposed Respondents"). The Commission's Bureau of Consumer Protection ("BCP") has prepared a draft of an administrative Complaint ("draft Complaint"). BCP and Proposed Respondents, individually or through their duly authorized officers enter into this Agreement Containing Consent Order ("Consent Agreement") to resolve the allegations in the attached draft Complaint through a proposed Decision and Order to present to the Commission, which is also attached and made a part of this Consent Agreement.

IT IS HEREBY AGREED by and between Proposed Respondents and BCP, that:

1. The Proposed Respondents are:

   a. Proposed Respondent Sunday Riley Modern Skincare, LLC, a Texas limited liability company with its principal office or place of business at 4444 Westheimer Road, Suite G305 Houston, Texas 77027-4455.

   b. Proposed Respondent Sunday Riley, an officer of Proposed Corporate Respondent, Sunday Riley Modern Skincare, LLC. Individually or in concert with others, she formulates, directs, or controls the policies, acts, or practices of Sunday Riley Modern Skincare, LLC. Her principal office or place of business is the same as that of Sunday Riley Modern Skincare, LLC.

QUESTIONS?