24th Annual Pharmaceutical & Medical Device Compliance Congress

Sponsored by Pharmaceutical Compliance Forum
October 25-27, 2023
Gaylord National Resort & Convention Center
National Harbor, MD

The Latest in Social Media Enforcements

October 25, 2023

Nikki Reeves- Moderator
Partner and Co-chair, Life Sciences and Healthcare Industry Group
King & Spalding

Sarah diFrancesca, JD
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Incyte

Elizabeth Hall, JD
Vice President, Commercial Counsel
Alkermes, Inc

Paul Silver
Principal and Corporate Intelligence Services Practice Leader
Deloitte

Today's Topics

- FDA and FTC Guidance and Enforcement
- AKS: FMV for DOLs and other Compliance Considerations
- Selection of Influencers, Content, Platform, Training
- HCP, Patient, and Celebrity Influencers

FDA Guidances on Internet and Social Media

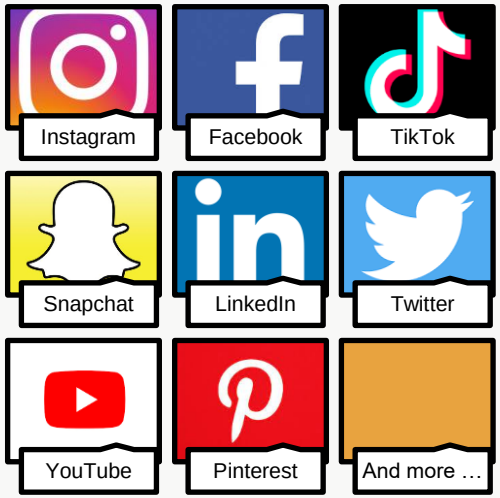
Draft Guidance	Date
Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*	January 2014
Internet/Social Media Platforms with Character Space Limitations – Presenting Risk Information for Prescription Drugs and Medical Devices	June 2014
Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices	June 2014

*CDER / CBER guidance

Advertising and Promotion on the Internet and Social Media

Advertising and promotion on the Internet and social media is subject to all the same requirements as traditional print advertising and promotion

> *"It's the message and not the medium, so we expect the same regulations to apply to social media such as Facebook…."*
>
> — Thomas Abrams, Former Director,
> Office of Prescription Drug Promotion (OPDP)



Endorsement of Patient Testimonials Containing Drug Claims (June 2014)

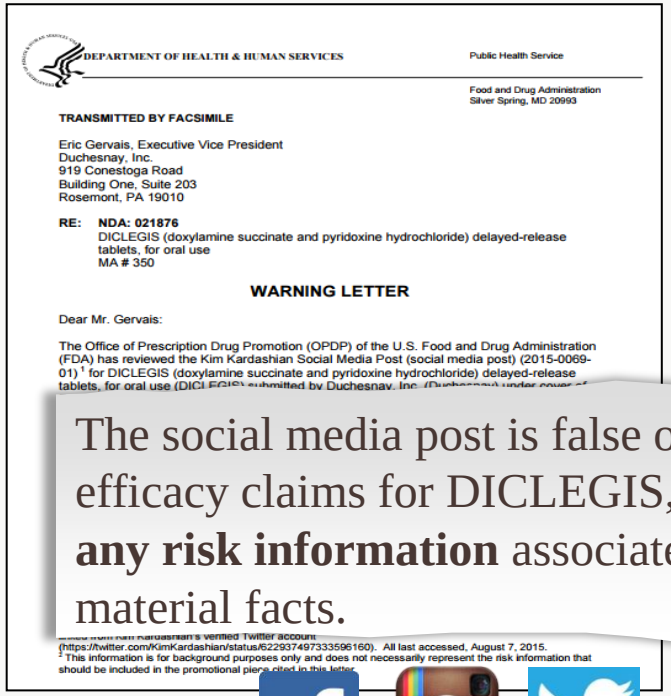
Mary (a consumer) wrote: *"…I received your…Zarbee's Naturals Children's Sleep Product. I have a daughter…born with cerebral palsy and she suffers from Complex Regional Pain Syndrome… [s]he took the samples you sent and slept through the night…best sleep she has had in years…"*

Zarbee's "liked" the comment: *"…Children's Sleep remedy…I received the free sample…and…gave it to my daughter…I could not believe how well it worked! She was recently diagnosed with ADHD and put on medication…causing insomnia…"*

Zarbee's commented *"Mary, Thank you for writing this!!! We love to hear that we have helped people..."*

FDA Warning Letter to Zarbee's (June 2014)

DICLEGIS Warning Letter (Aug. 2015)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

TRANSMITTED BY FACSIMILE

Eric Gervais, Executive Vice President
Duchesnay, Inc.
919 Conestoga Road
Building One, Suite 203
Rosemont, PA 19010

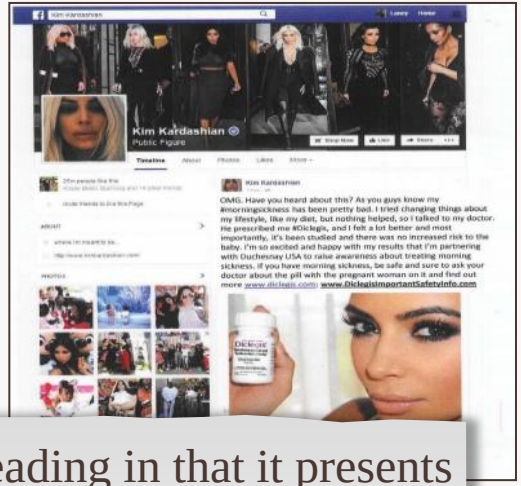
RE: NDA: 021876
DICLEGIS (doxylamine succinate and pyridoxine hydrochloride) delayed-release tablets, for oral use
MA # 350

WARNING LETTER

Dear Mr. Gervais:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the Kim Kardashian Social Media Post (social media post) (2015-0069-01)[1] for DICLEGIS (doxylamine succinate and pyridoxine hydrochloride) delayed-release tablets, for oral use (DICLEGIS), submitted by Duchesnay, Inc. (Duchesnay), under cover of

[1] Posted from Kim Kardashian's verified Twitter account (https://twitter.com/KimKardashian/status/622937497333596160). All last accessed, August 7, 2015.
[2] This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional piece cited in this letter.



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

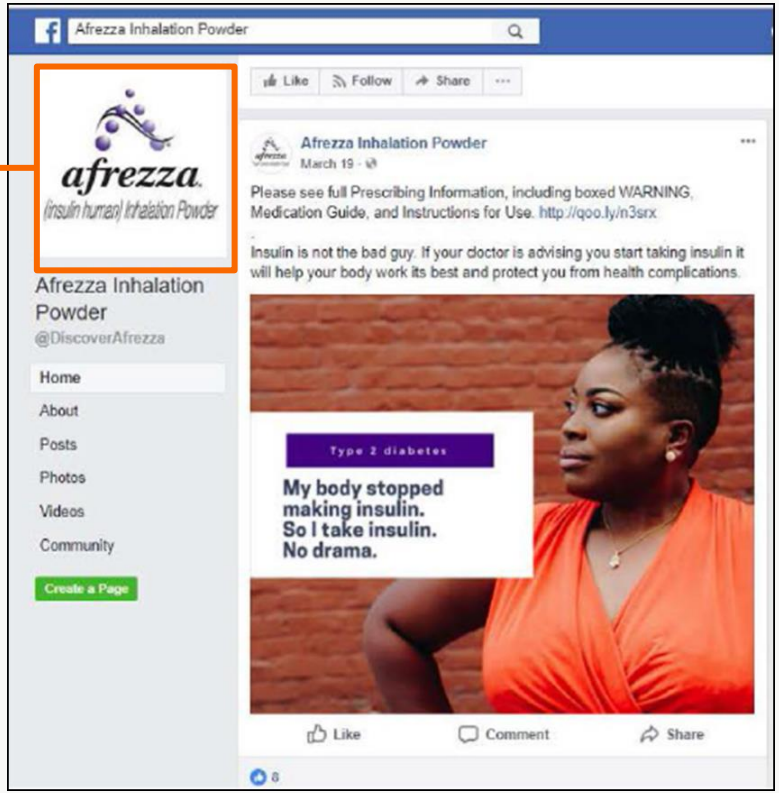
AFREZZA Warning Letter (Oct. 2018)

Directional statement to PI does not mitigate the misleading impression

Risk information must

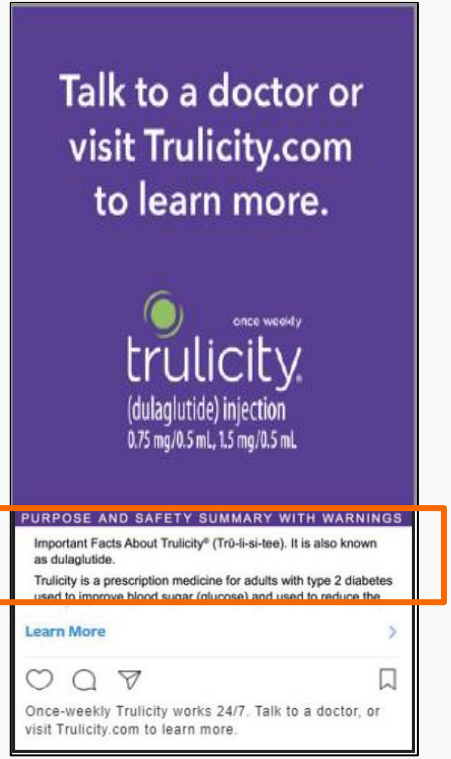
- ✓ Be visible
- ✓ Adequately disclose important information

Separate pop-up box appeared with indication and limited risk information when hovering over the Afrezza logo



TRULICITY Untitled Letter (Jan. 2022)

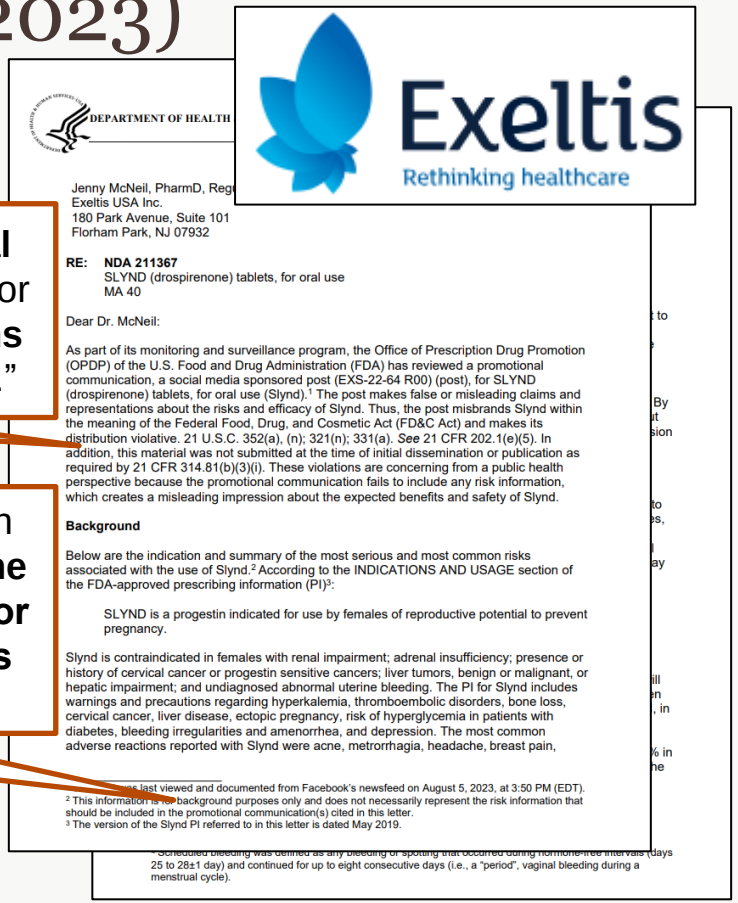
"[T]he risk information is in a small window, relegated to the bottom of the post and is presented using fact-paced, scrolling, small font that is difficult to read and cannot be adequately processed or comprehended by consumers." - OPDP



SLYND Untitled Letter (Aug. 2023)

"[OPDP] has reviewed a promotional communication, **a social media sponsored post** ... for SLYND (drospirenone) tablets, for oral use (Slynd). **The post makes false or misleading claims and representations about the risks and efficacy of Slynd**."

"This claim ['Offer your patients estrogen-free birth control with periods on a schedule'] is misleading because **it overstates the efficacy of Slynd by claiming patients will have a 'period,' or bleeding, that is predictable and 'on a schedule' when this has not been demonstrated.**"



DEPARTMENT OF HEALTH

Exeltis
Rethinking healthcare

Jenny McNeil, PharmD, Reg
Exeltis USA Inc.
180 Park Avenue, Suite 101
Florham Park, NJ 07932

RE: **NDA 211367**
SLYND (drospirenone) tablets, for oral use
MA 40

Dear Dr. McNeil:

As part of its monitoring and surveillance program, the Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed a promotional communication, a social media sponsored post (EXS-22-64 R00) (post), for SLYND (drospirenone) tablets, for oral use (Slynd).[1] The post makes false or misleading claims and representations about the risks and efficacy of Slynd. Thus, the post misbrands Slynd within the meaning of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and makes its distribution violative. 21 U.S.C. 352(a), (n); 321(n); 331(a). *See* 21 CFR 202.1(e)(5). In addition, this material was not submitted at the time of initial dissemination or publication as required by 21 CFR 314.81(b)(3)(i). These violations are concerning from a public health perspective because the promotional communication fails to include any risk information, which creates a misleading impression about the expected benefits and safety of Slynd.

Background

Below are the indication and summary of the most serious and most common risks associated with the use of Slynd.[2] According to the INDICATIONS AND USAGE section of the FDA-approved prescribing information (PI)[3]:

> SLYND is a progestin indicated for use by females of reproductive potential to prevent pregnancy.

Slynd is contraindicated in females with renal impairment; adrenal insufficiency; presence or history of cervical cancer or progestin sensitive cancers; liver tumors, benign or malignant, or hepatic impairment; and undiagnosed abnormal uterine bleeding. The PI for Slynd includes warnings and precautions regarding hyperkalemia, thromboembolic disorders, bone loss, cervical cancer, liver disease, ectopic pregnancy, risk of hyperglycemia in patients with diabetes, bleeding irregularities and amenorrhea, and depression. The most common adverse reactions reported with Slynd were acne, metrorrhagia, headache, breast pain,

[1] [illegible] last viewed and documented from Facebook's newsfeed on August 5, 2023, at 3:50 PM (EDT).
[2] This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional communication(s) cited in this letter.
[3] The version of the Slynd PI referred to in this letter is dated May 2019.

[illegible] Scheduled bleeding was defined as any bleeding or spotting that occurred during hormone-free intervals (days 25 to 28±1 day) and continued for up to eight consecutive days (i.e., a "period", vaginal bleeding during a menstrual cycle).

King & Spalding

Continued FTC & FDA Focus: Social Media Endorsements & Testimonials

Influencer communications must meet all FDA regulatory requirements for promotional labeling

Influencers engaged by advertisers must disclose the nature of their relationship clearly and conspicuously

Higher Risk Influencer Claims

Minimization of risk

Overstatement of efficacy

Quality of life claims

Comparative / Superiority Claims

#Ad #Sponsored

✓ Prominently placed

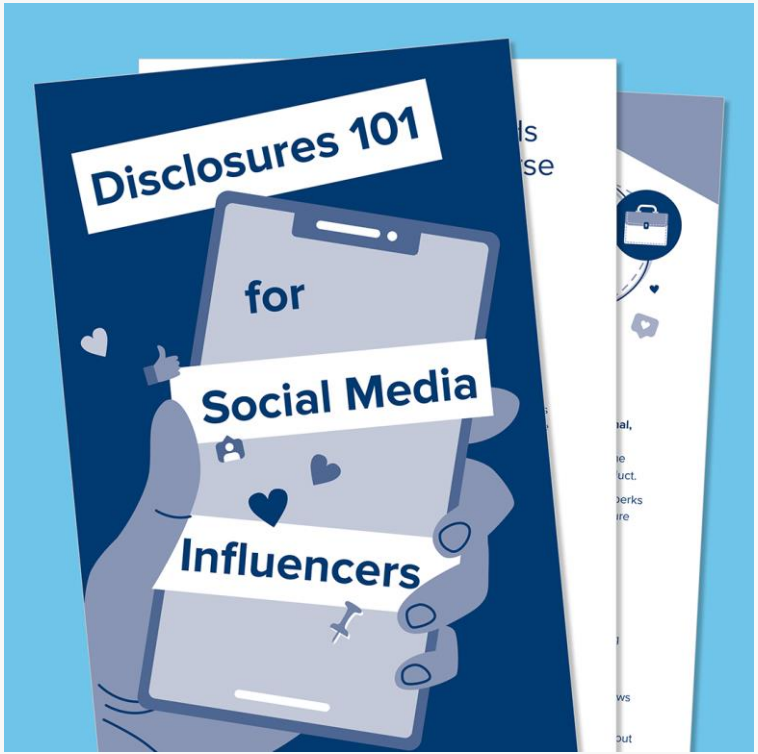
✓ Not #buried #within #hashtags

✓ *In a font that is easy to read*

✓ In a shade that stands out

FTC Guidance Updates: Influencer Marketing & Native Advertising

- "FTC's Guides Concerning the Use of Endorsements and Testimonials in Advertising" (Updated 2023)
- FTC "Dot Com Disclosures" Guidance (2013)
- FAQs: "The FTC's Endorsement Guides What People Are Asking" (Updated 2017)
- FTC Tweet Chat on Social Media Influencers (September 2017)
- Disclosures 101 for Social Media Influencers (November 2019)



Digital Opinion Leaders "DOL" FMV

Deloitte.

Patient influencers are going viral

But what does it mean for HCP fair market value (FMV)?

Social media influencers and a subset group known as "patient influencers," can be patients, physicians, patient advocates, nurses, and others who are involved in delivering or receiving care. They have become a part of the health care system and are now significant voices providing educational and promotional support to the life sciences industry.

Social media has changed the marketing landscape of the life sciences industry in many ways, but in particular, the way in which information is provided, disseminated, and gathered.

Interactions and engagements specific to social media differ from those of the traditional FMV model with HCPs. Nonetheless, the concept of FMV continues to apply. These interactions go beyond the hourly level of effort of a social influencer whereby the FMV will depend on the social media platform, number of followers of the influencer, and relevance of the content, among other factors.

Likes

Research has shown that among patient influencers:

94%
utilize social media to advocate on a specific health condition or topic

80%
turn to social media to connect with peers and access support

94%
say that online communities play at least a "somewhat important" role in their health conditions

Challenges

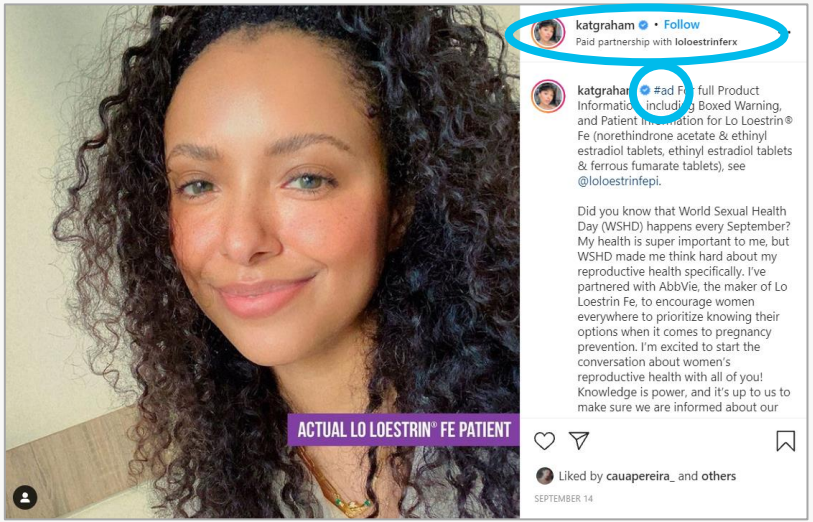
The use of social influencers by life sciences companies is relatively new and carries regulatory risk related to the Federal Trade Commission (FTC), US Food and Drug Administration (FDA), fair and balanced disclosures, Anti-Kickback Statute, and the Stark Law. Therefore, companies must remain vigilant and ethical in their pursuit to expand their reach.

Now is an opportune time for companies to assess their end-to-end HCP engagement processes to help ensure the policies, processes, and controls - including those related to FMV - are aligned to govern this new way of working.

K&S King & Spalding

Social Media Influencers: *FTC Requirements for Adequate Disclosure*

If the company is compensating an individual for social media posts or otherwise involved in the development of the tweet or post, that relationship must be clearly and prominently disclosed.



Deloitte.

DR. IMA PERSON, MD, IBCLC
@dr.imaperson (IG, TT & YT)
@personpediatrics (FB)

Dr. Ima Person is a board-certified pediatrician, IBCLC, and mother. She uses her social channels to educate on both pediatrics and parenting and is most active across her TikTok and Instagram channels. She also contributes regularly to press and media as an AAP Media Spokesperson.

TIKTOK

193.8K Followers (MID)
ER: 0.99%

Video: ***$1,000 – $2,000***

TikTok is Dr. Ima's most followed channel and also has the highest follower growth rate. The majority of her content is filmed "selfie-style" and covers a wide range of topics from relatable mom moments and pediatric tips to reacting to posts shared by other creators on the platform, in which she includes her doctor POV.

YOUTUBE

7.4K Followers (MICRO)
ER: 0.72%

Video: ***$100***

While Dr. Ima is not posting as regularly to her YouTube channel as she does on Instagram and YouTube, she is sharing an avg. of 3 videos per month. This content includes longer-form, more edited videos centered around general parenting & pediatrician-backed tips.

INSTAGRAM

67K Followers (MICRO)
ER: 2.82%

Reel: ***$500 - $800***

Story: ***$170 - $300***

Instagram is Dr. Ima's 2nd most followed channel, although it has seen follower loss in recent months. There is some crossover with the content that she shares on TikTok, however, her Instagram content appears to be more regularly focused on health-related topics. Additionally, her engagement rate on the platform is much higher than TikTok.

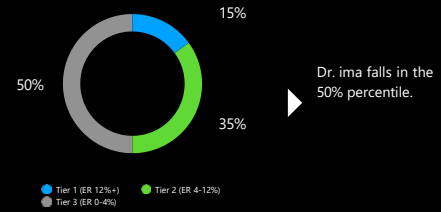
FACEBOOK

1.2K Followers (MICRO)
ER: 0.04%

Post: ***$50***

Facebook is Ima's smallest following. While she does keep up a steady cadence of posting, majority of his content is auto-reposted from his IG. She also shared news of his partnership with Janssen, which performed the lowest on this platform.

ENGAGEMENT TIERS



AUDIENCE DEMOGRAPHICS:

GENDER	IG	YT	TT	FB
	82%	82%	85%	N/A
	18%	18%	15%	N/A

TOP 3 GLOBAL CITIES (IG only)	
New York City, USA	6%
Los Angeles, USA	3%
Chicago, USA	2%

AGE	IG	YT	TT	FB
18-20	11%	23%	23%	N/A
21-29	42%	52%	49%	N/A
30-44	27%	21%	20%	N/A
45+	3%	1%	2%	N/A

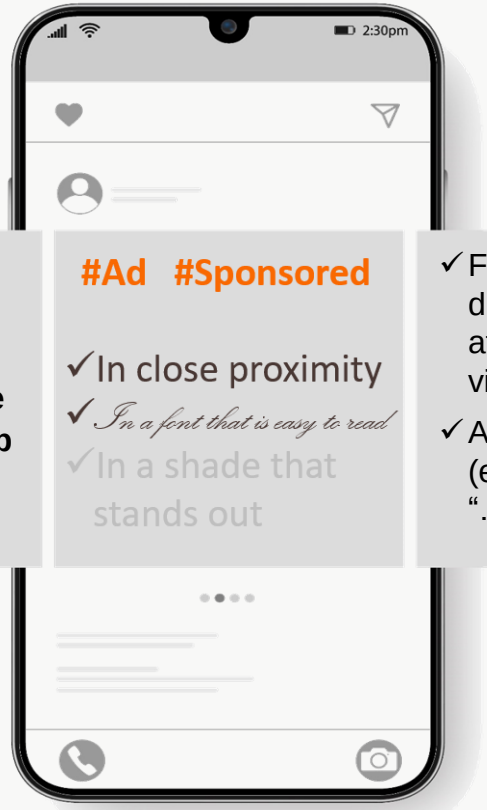
DR. IMA'S CONTENT

INSTAGRAM
TIKTOK
FACEBOOK
YOUTUBE

King & Spalding

Clear & Conspicuous Disclosures of Material Connection

Influencers engaged by advertisers must disclose the nature of their relationship clearly and conspicuously



#Ad #Sponsored

✓In close proximity

✓*In a font that is easy to read*

✓In a shade that stands out

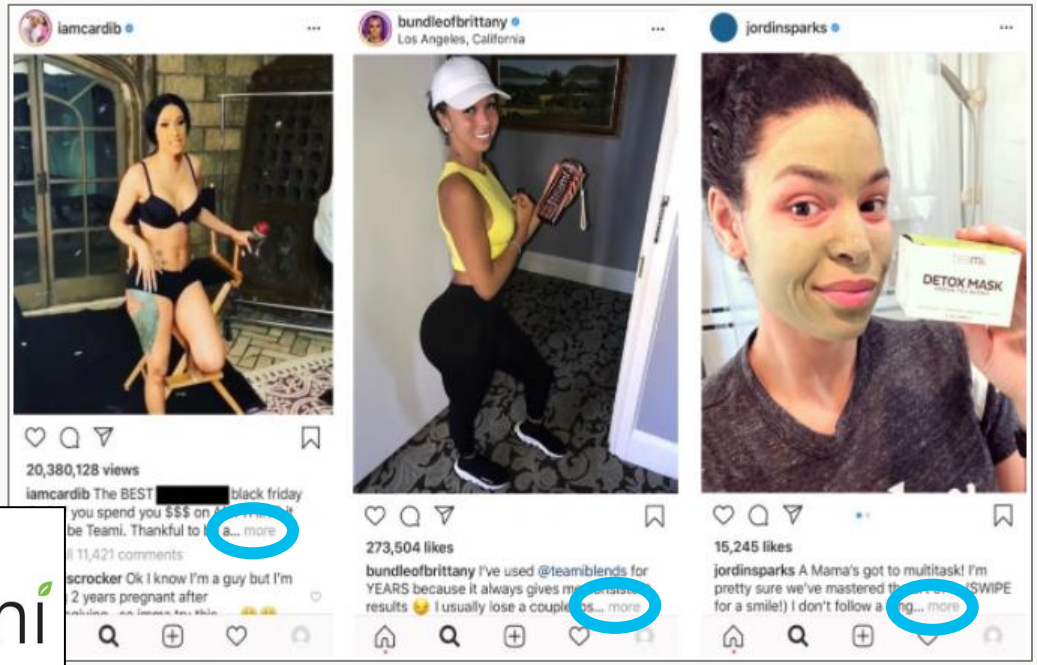
- ✓For videos, displayed on screen at the beginning of video and in caption
- ✓Above the fold (e.g., above the "… more" line)

- ✓In words consumers will understand
- ✓NOT #buried #among #hashtags
- ✓Do NOT rely on platform tools alone

FTC Enforcement: Teami (Mar. 2020)

Misleading weight loss claims for Teami's 30 Day Detox Pack through website and paid influencers' Instagram posts

Disclosure that the endorsements were paid were not visible unless users clicked the "**… more**" option

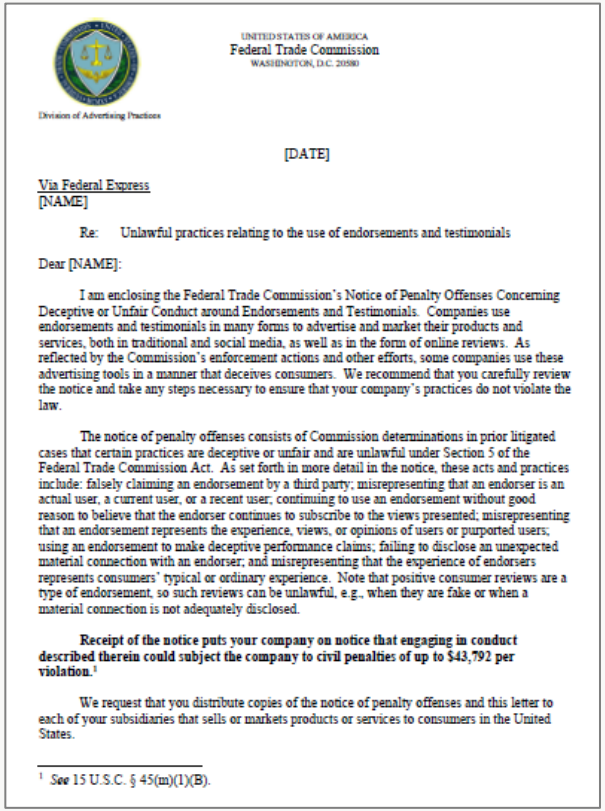


FTC Notice of Penalty Offenses (Oct. 2021)

FTC Notice of Penalty Offenses Concerning Deceptive or Unfair Conduct around Endorsements and Testimonials

Sent to more than **700 companies**, including several pharmaceutical companies

Receipt of the letter puts companies on notice that future violations can subject the company to **civil penalties of up to $43,792 per violation**



UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Division of Advertising Practices

[DATE]

Via Federal Express
[NAME]

Re: Unlawful practices relating to the use of endorsements and testimonials

Dear [NAME]:

I am enclosing the Federal Trade Commission's Notice of Penalty Offenses Concerning Deceptive or Unfair Conduct around Endorsements and Testimonials. Companies use endorsements and testimonials in many forms to advertise and market their products and services, both in traditional and social media, as well as in the form of online reviews. As reflected by the Commission's enforcement actions and other efforts, some companies use these advertising tools in a manner that deceives consumers. We recommend that you carefully review the notice and take any steps necessary to ensure that your company's practices do not violate the law.

The notice of penalty offenses consists of Commission determinations in prior litigated cases that certain practices are deceptive or unfair and are unlawful under Section 5 of the Federal Trade Commission Act. As set forth in more detail in the notice, these acts and practices include: falsely claiming an endorsement by a third party; misrepresenting that an endorser is an actual user, a current user, or a recent user; continuing to use an endorsement without good reason to believe that the endorser continues to subscribe to the views presented; misrepresenting that an endorsement represents the experience, views, or opinions of users or purported users; using an endorsement to make deceptive performance claims; failing to disclose an unexpected material connection with an endorser; and misrepresenting that the experience of endorsers represents consumers' typical or ordinary experience. Note that positive consumer reviews are a type of endorsement, so such reviews can be unlawful, e.g., when they are fake or when a material connection is not adequately disclosed.

Receipt of the notice puts your company on notice that engaging in conduct described therein could subject the company to civil penalties of up to $43,792 per violation.[1]

We request that you distribute copies of the notice of penalty offenses and this letter to each of your subsidiaries that sells or markets products or services to consumers in the United States.

[1] *See* 15 U.S.C. § 45(m)(1)(B).