20th Annual Pharmaceutical and Medical Device Compliance Congress

MINI SUMMIT 23: SOCIAL MEDIA ENGAGEMENT BY MANUFACTURERS

November 7, 2019

AGENDA

- Welcome and Introductions
- Social Media Regulatory Overview
  - Draft Guidances
  - Enforcement Letters
- Q&A

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- **Welcome and Introductions**
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Social Media Regulatory Overview

- No FDA law or regulation specifically addresses internet or social media promotion, **BUT** basic promotional principles still apply.
- According to FDA, it's the message not the medium that matters most.
- Promotional claims **must**:

1. Not be false or misleading
2. Have "fair balance" and not minimize risk
3. Be substantiated
4. Not discuss unapproved ("off-label") uses

Social Media Regulatory Overview

- In 2014, FDA issued three draft guidances relevant to social media:
  - Internet/Social Media Platforms with Character Space Limitations--Presenting Risk and Benefit 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)
  - Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (Jan. 2014)
- FDA's 2011 guidance on responding to unsolicited requests for off-label information addresses questions encountered through electronic/social media platforms.
  - Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (Dec. 2011)

Twitter and Character Space Limited Platforms

- Draft guidance applies traditional advertising rules to modern platforms
- What should be included in each message?
  - Product name (for drugs, both proprietary and established)
  - Benefits/material facts (e.g., limitations to indication)
  - Most serious risks
  - Hyperlink to risk information landing page
- Guidance focuses on branded promotion on Twitter and other character space limited platforms; other types of communications are not subject to the guidance, e.g.:
  - Unbranded disease communications
  - Non-promotional corporate communications, such as tweeting a link to a press release

Draft guidance: Presenting Risk and Benefit Information Internet/Social Media Platforms with Character Space Limitations (2014)

Correcting Misinformation

- Draft guidance describes FDA's thinking on manufacturers' voluntary correction of misinformation disseminated by an independent third-party on social media
  - Misinformation: Positive or negative incorrect representations or implications about a firm's product
- Manufacturers may provide "appropriate corrective information" that `
  - Is accurate and non-misleading
  - Is responsive and tailored to the misinformation
  - Is non-promotional in nature, tone, and presentation
  - Is consistent with FDA-required labeling and supported by sufficient evidence
  - Is posted (or intended to be posted) in conjunction with the misinformation
  - Discloses affiliation of person correcting the misinformation with the manufacturer
  - Includes a link to the PI that is not hosted on a promotional website
  - Identifies the date and the portion of the forum it is correcting (e.g. that it is only correcting a certain comment)

Draft guidance: Correcting Independent Third-Party Misinformation on Internet/Social Media Platforms (2014)

Regulatory Requirements for Submissions of Interactive Promotional Media

- A manufacturer is responsible for product promotion
  - On sites that are owned, controlled, created, influenced, or operated by, or on behalf of, the firm
  - On third-party sites over which it has control or influence, even if that influence is limited
- However, FDA does not consider user generated content ("UGC") that is "truly independent" to be promotional content on behalf of the manufacturer
- UGC is "truly independent" if it is not produced by, or on behalf of, or prompted by the firm in any particular, which is generally met where:
  - The user has no affiliation with the firm
  - The firm had no influence on the UGC
- Guidance addresses 2253 submission requirements

Draft guidance: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media (2014)

Responding to Unsolicited Requests for Off-Label Information

- Reflects agency thinking regarding responding to public and non-public, unsolicited requests for off-label information regarding approved/cleared medical products;
- Public requests can arise through various social media platforms which manufacturers may or may not control. Responding to such requests raises agency concerns:
  - Responses likely to be available to those who did not request the information
  - Responses likely to be enduring and may become outdated
- When responding to public, unsolicited requests publicly, FDA advises:
  - Response should be limited to providing firm's contact information and should ***not*** include any off-label information
  - Response should convey that question pertains to an unapproved or uncleared use of the product and should suggest requestor contact the medical/scientific representative or medical affairs department to obtain more information and should provide specific contact information
  - Representatives responding publicly should clearly disclose involvement with the manufacturer
  - Such responses should not be promotional in nature or tone

Draft guidance: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (Dec. 2011)

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Social Media Warning / Untitled Letters (Selected)

Corporate / consumer websites	▪ Untitled Letter to VIVUS, Inc. (May 2019) (FDA alleges company website includes misleading messages and omits key information about Qysmia).
Banner ads (shown across several websites)	▪ Warning Letter to Metuchen (August 2019) (FDA alleges that banner ad slogans make misleading claims and/or representations about risks associated with Stendra)
YouTube	▪ Untitled Letter to Kowa (Sept. 2019) (FDA alleges DTC patient testimonial montage/video makes misleading clams and/or representations about risks associated with Livalo)
Facebook	▪ Warning Letter to MannKind (October 2018) (FDA alleges company Facebook page suggested there are no risks associated with drug Affreza because drug would "protect you from health complications" with "no drama" ▪ Warning Letter to AMARC Enterprises (December 2012) (FDA alleges company's "liking" of a customer comment about an unapproved use constituted an unapproved drug claim)
Sponsored links (e.g., Google ads)	▪ Untitled Letters to 14 companies (March 2009) (FDA alleges sponsored links lacked fair balance and were misleading due to exclusion of risk information.)
Other Social Media sites	▪ Warning Letter to Duchesnay (August 2015) (FDA alleges Instagram/FB/Twitter (influencer) post did not communicate risk information and omitted material limitations on use of Diclegis) ▪ Warning Letter to doTERRA (September 2014) (FDA alleges that 15 of company's Essential Oils products were being promoted on Twitter, Pinterest, YouTube and Facebook for drug intended uses, including for treating Ebola, MRSA, shingles, Hepatitis C, H1N1 and others)
Metatag keywords (used to bring consumers to website)	▪ Warning Letter to John Gray's Mars Venus LLC (February 2018) (FDA alleges that website is making unapproved drug claims for various products, and that claims are supplemented by metatag keywords used to bring consumers to the website from internet searches)

Banner ads: Omits Risk Information / Overstates Efficacy

- Metuchen Pharmaceuticals, Aug. 2019
- Warning Letter re: Stendra (avanafil)
- Issue: Banner ads omit risk and other material information, and claim “indulge in life’s sweetest pleasures whenever you want” found to be a misleading claim about the risks associated with and efficacy of Stendra. PI states “the maximum recommended dosing frequency is once per day” and the efficacy of the drug is between “15 minutes and 2 hours of dosing.”

----------DOSAGE AND ADMINISTRATION----------

- For most patients, the starting dose is 100 mg taken approximately 30 minutes before sexual activity, on an as needed basis (2.1)
- Take STENDRA no more than once a day (2.1).

YouTube DTC Video: Minimization of Risk

- Kowa Pharmaceuticals America, Sep. 2019
- Untitled Letter re: Livalo (pitavastatin)
- Issue: DTC patient testimonial video montage created a misleading impression that patients on Livalo would experience fewer side effects than associated with other statins, and deemphasized the risks associated with taking the drug.

Debbie D.

VOICEOVER (VO) (:04 - :06): "When I did the cholesterol panel, mine was extremely high."
SUPER: **my** switch to **LIVALO®**
Debbie D. Switched statins 6 times due to side effects

VO (:45 - :48): "After I took LIVALO, I've had no pain and my cholesterol levels are down."
SUPER: **my** switch to **LIVALO®**
Debbie D. Taking LIVALO for 3 years

Donnie W.

VO (:07 - :10): "My doctor recommended I start with a statin. We started with one, we had a lot of side effects."
SUPER: **my** switch to **LIVALO®**
Donnie W. Switched statins 4 times due to side effects

VO (:31 - :35): "LIVALO definitely made a positive impact in reducing my cholesterol and reduced side effects."
SUPER: **my** switch to **LIVALO®**
Donnie W. Taking LIVALO for 8 years

Robert M.

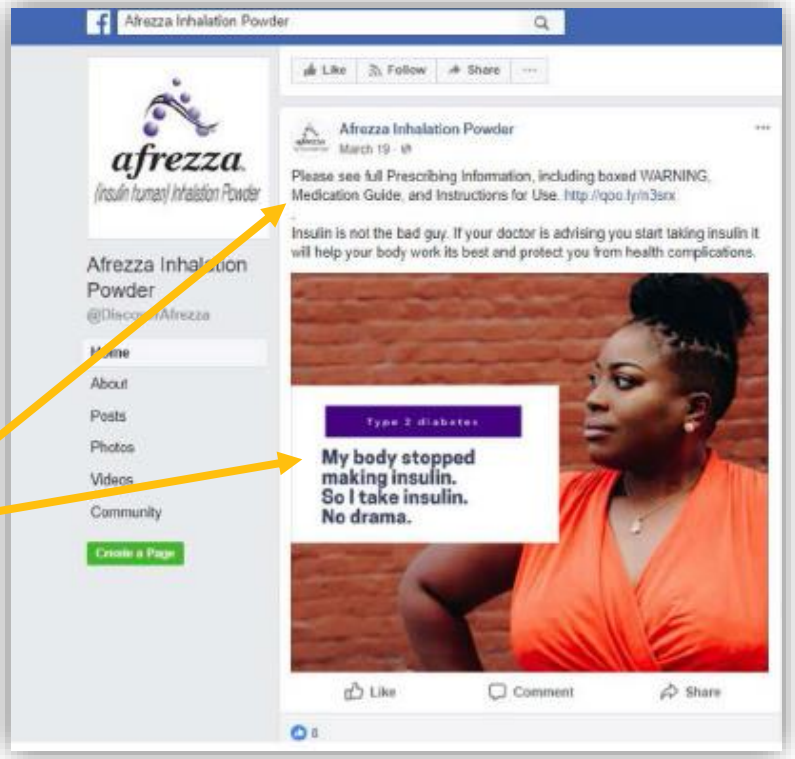
VO (:11 - :19): "The first medication I went on came with a lot of side effects, so I tried other ones after that and it was even worse."
SUPER: **my** switch to **LIVALO®**
Robert M. Switched statins 3 times due to side effects

VO (:36 - :44): "I wish I was put on LIVALO years ago, because I'm not having the side effects that I was having with the other statins."
SUPER: **my** switch to **LIVALO®**
Robert M. Taking LIVALO for 4 years

Facebook Post: Minimize Risks

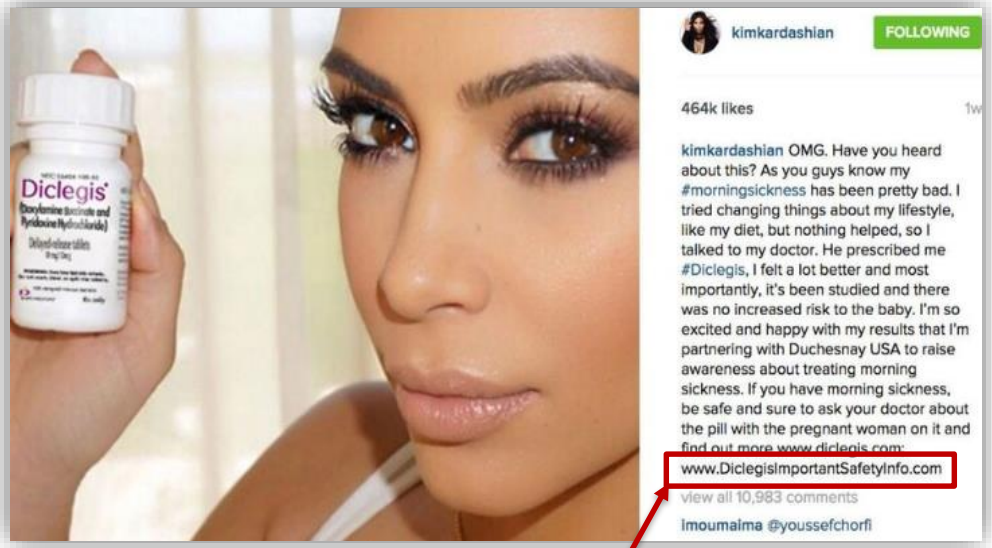
- MannKind Corporation, Oct. 2018
- Warning Letter re: Afrezza (insulin human)
- Issue: Claims on the Facebook post suggested that the drug had no risks

"This post suggests that there are no risks associated with the use of the drug . . . the post claims that "Afrezza Inhalation Powder" "will help your body work its best and protect you from health complications" with "no drama," when . . . Afrezza is associated with multiple serious, and potentially life-threatening risks, such as those contained in the product's BOXED WARNING."



Influencers: Facebook, Twitter, Instagram Posts

- Duchesnay, Inc., Aug. 2015
- Warning Letter re: Diclegis (doxylamine succinate and pyridoxine hydrochloride)
- Issue: Instagram, FB, and Twitter post from Kim K. false or misleading; presented efficacy claims, but failed to communicate any risk information and omitted material facts (i.e., was not studied in women with hyperemesis gravidarum)



Link to important safety info did not mitigate omission

Facebook “Like”: Create Claim

- AMARC Enterprises, Dec. 2012
- Warning Letter re: Poly-MVA
- Issue: FDA identified multiple examples of unapproved drug claims, including a customer comment on the company’s Facebook page, which the company had “liked”

This letter concerns your firm’s marketing of the products, Poly-MVA and Poly-MVA for Pets. The U.S. Food and Drug Administration (FDA) reviewed your websites, www.polymva.com and www.polymva.net, as well as literature included in the information packet which accompanied the sale and shipment of your product, “Poly MVA” on November 15 and has determined that “Poly MVA” is promoted for conditions that cause the product to be a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The claims in the literature and on your websites establish that this product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of your product with these claims violates the Act.

In a March 10, 2011 post which was “liked” by “Poly Mva”:

- “PolyMVA has done wonders for me. I take it intravenously 2x a week and it has helped me tremendously. It enabled me to keep cancer at bay without the use of chemo and radiation…Thank you AMARC”

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