How to avoid “going viral” with the FDA

October 29, 2019 12:00-1:00pm

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Agenda

- Why social media?
- FDA guidance and rules
- Common pitfalls
- Social media and web-related enforcement examples and trends
  - Warning letters
  - Real world examples
- Best practices
- Takeaways

Why Social Media

Pros

- Free (usually)
- Viewed as low investment
- Option to be active or passive (Like, post, share, comment v. post only)
- Ability to reach a large audience
- Ability to reach a select audience (targeted ads)
- Viral nature of social media is enticing.

Cons

- May require a large resource investment (review, monitoring, etc.)
- Being active can be risky, but so can being passive
- Broad audience reach
- Disclosure of risk and safety information
- Including fair and balanced information
- Viral nature of social media is enticing

FDA Guidance & Rules

Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information

- Benefit and risk information must be:
  - Accurate, non-misleading, balanced;
  - Disclosed together with all material facts; and
  - In the same message (tweet, post, paid search/sponsored links)
- Risk information must be "comparable" to benefits in scope, content, prominence, and readability
- At minimum, include most serious risks (e.g., boxed warning, life-threatening, risks to specific populations)
- Include direct link to landing page with complete risk info (e.g., Brief Statement)
  - No promotional messaging
- Use formatting (if available) to highlight significant risk information (e.g., boxed warning should be bolded)

Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescriptions Drugs and Medical Devices

- Companies can choose to correct misinformation about its own products or ask the author to remove misinformation
- Defines a “safe harbor” that allows companies to correct misinformation without being subjected to more stringent promotional labeling requirements
- Should not “cherry pick” and only correct negative misinformation, while leaving misinformation that is beneficial
- If the company’s corrective information does not follow guidance, then it is not covered by the “safe harbor” and all promotional labeling rules apply

Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices

- Defines “safe harbor” and if followed, FDA does not intend to use company’s response as evidence of intent that the product be used for an unapproved/uncleared use.
- Response requirements:
  - Respond only when the request pertains specifically to its own named product (and not solely about a competitor’s product);
  - Company’s public response should state that the question relates to unapproved use and direct them medical affairs with specific contact information;
  - Do not provide detailed response in public forum;
  - Disclose affiliation with company;
  - Must not be promotional in nature or tone; and
  - Provide direct link to FDA-required labeling (not website with promotional content).

Paid Search, Sponsored Links, SEO

- FDA's character limitation guidance applies
- For drugs, "reminder ad" guidance may be applicable
  - If only the drug's name is disclosed and not the use/benefits, then risk information is not required
- All search keywords, metatags, and ad content should be consistent with labeling, accurate, and non-misleading

Common Pitfalls

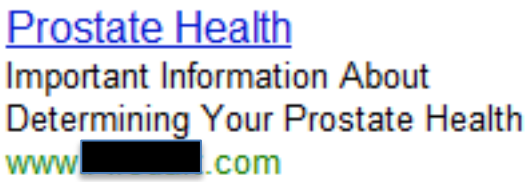
Common Pitfalls

- Not having policies/procedures regarding social media use
- Failure to provide balanced risk information
- No plan for content/posts
- Not identifying a lead employee to post
- Failing to internally review/approve content
- Failing to monitor social media
- Not following FDA guidance when correcting misinformation
- Responding inappropriately to off-label questions
- Off-label or inappropriate metatags, SEO, paid search terms
- No plan for responding to DMs or comments
- Liking, commenting, sharing, retweeting, etc.

Enforcement Examples & Trends

Warning Letters related to Google Advertising

- On March 26, 2009, FDA sent Warning Letters to 14 pharma companies in one day related to Google Advertising
- Warning Letters covered five specific topics:
    1. Omitting risk information
    2. Minimizing risk information
    3. Inadequately communicating indications
    4. Overstating efficacy
    5. Failing to use established brand names
- FDA views internet search advertising itself as a complete advertisement



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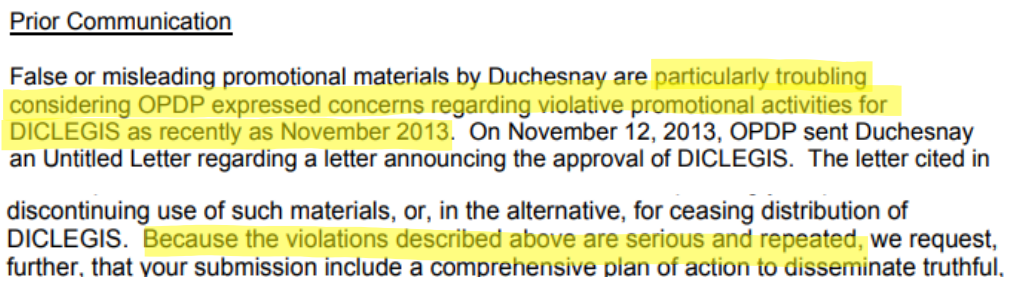
Warning Letter – Duchesnay, Inc.

- August 7, 2015
- Pharmaceutical company
  - DICLEGIS (doxylamine succinate and pyridoxine hydrochloride)
    - Indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.
- Instagram, Facebook, and Twitter post made by Kim Kardashian
  - Not the first time OPDP had expressed concerns regarding companies promotional activities.



Prior Communication

False or misleading promotional materials by Duchesnay are particularly troubling considering OPDP expressed concerns regarding violative promotional activities for DICLEGIS as recently as November 2013. On November 12, 2013, OPDP sent Duchesnay an Untitled Letter regarding a letter announcing the approval of DICLEGIS. The letter cited in

discontinuing use of such materials, or, in the alternative, for ceasing distribution of DICLEGIS. Because the violations described above are serious and repeated, we request, further, that your submission include a comprehensive plan of action to disseminate truthful,

- FDA stated that risk info was not included and the link to the ISI was not sufficient.

Warning Letter – Duchesnay, Inc.

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 Form FDA 2253. The social media post was also submitted as a complaint to the OPDP Bad Ad Program. 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. Thus, the social media post misbrands DICLEGIS 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). These violations are concerning from a public health perspective because they suggest that DICLEGIS is safer than has been demonstrated.

https://www.fda.gov/media/93230/download

Warning Letter – Duchesnay, Inc.

Omission of Risk Information

Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made by the materials or with respect to consequences that may result from the use of the drug as recommended or suggested by the materials.

The social media post is misleading because it presents various efficacy claims for DICLEGIS, but fails to communicate any risk information. For example, the social media post includes the following claims:

The social media post, however, entirely omits **all** risk information. We note the statement, "[F]ind out more www.diclegis.com; www.DiclegisImportantSafetyInfo.com[,]" appears at the end of the social media post; however, this does not mitigate the misleading omission of risk information. By omitting the risks associated with DICLEGIS, the social media post misleadingly fails to provide material information about the consequences that may result from the use of the drug and suggests that it is safer than has been demonstrated.

Warning Letter – Duchesnay, Inc.

Omission of Material Fact

In addition, the social media post is misleading because it fails to provide material information regarding DICLEGIS' full approved indication, including important limitations of use. Specifically, it fails to convey that DICLEGIS has not been studied in women with hyperemesis gravidarum. The Indications and Usage section of the PI states the following (emphasis in original):

> **Limitations of Use**
>
> DICLEGIS has not been studied in women with hyperemesis gravidarum.

https://www.fda.gov/media/93230/download

Warning Letter – MannKind Corporation

- October 5, 2018
- Pharmaceutical company
  - AFREZZA (insulin human)
    - Rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus.
  - BOXED WARNING
    - risk of acute bronchospasm in patients with chronic lung disease.
- FDA pointed to a Facebook post.
- FDA stated that no risk information was included and link to ISI is not sufficient.

Warning Letter – MannKind Corporation

RE: **NDA 022472** AFREZZA® (insulin human) inhalation powder, for oral inhalation use MA 439

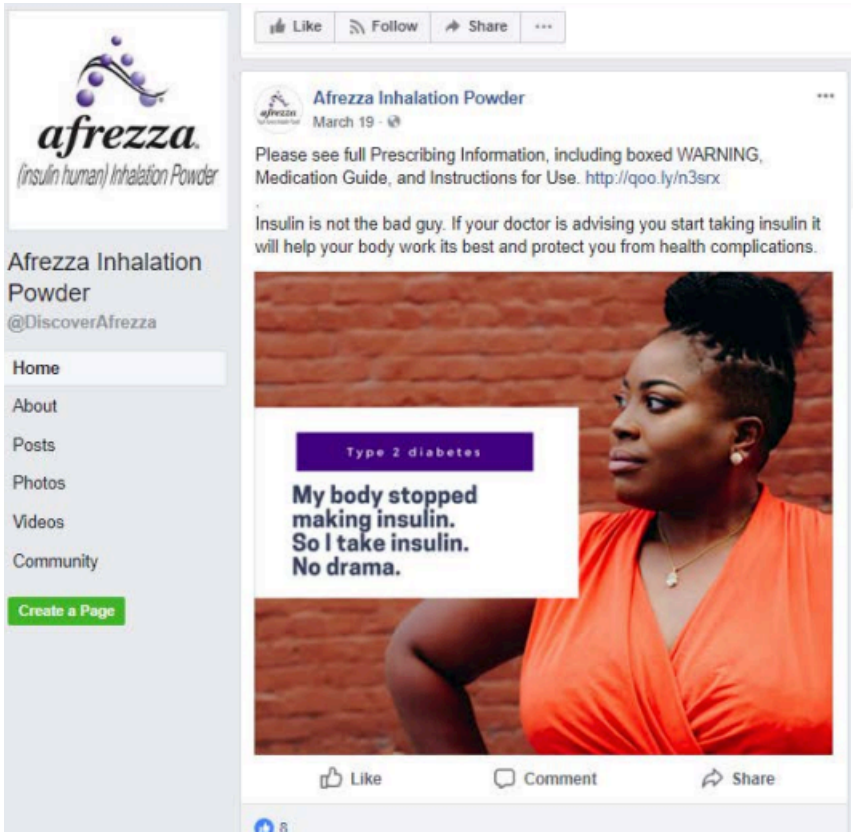
WARNING LETTER

Dear Dr. Castagna:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed a Facebook post (post) for AFREZZA® (insulin human) inhalation powder, for oral inhalation use (Afrezza) posted on on MannKind Corporation's (MannKind) Facebook page for Afrezza on February 9, 2018, and March 19, 2018.*1* The OPDP Bad Ad Program also received a complaint regarding posts on the Afrezza Facebook page. The post reviewed by OPDP makes false or misleading claims and/or representations about the risks associated with Afrezza by suggesting that there are no safety concerns associated with the use of the drug. Therefore, the post misbrands Afrezza within the meaning of the Federal Food, Drug and Cosmetic Act (FD&C Act), making its distribution violative. 21 U.S.C. 352(a), (n); 321(n), 331(a). See 21 CFR 202.1(e)(3); (e)(5). These violations are especially concerning from a public health perspective because Afrezza is a drug with multiple serious, potentially life-threatening risks, including a BOXED WARNING for the risk of acute bronchospasm in patients with chronic lung disease.

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mannkind-corporation-578282-10052018

Warning Letter – MannKind Corporation



This post suggests that there are no risks associated with the use of the drug. Specifically, in the context of a promotional piece for Afrezza, the post claims that "Afrezza Inhalation Powder" "will help your body work its best and protect you from health complications" with "no drama," when this may not be the case. As discussed in the Background section above, Afrezza is associated with multiple serious, and potentially life-threatening risks, such as those contained in the product's BOXED WARNING. By suggesting that there are no risks associated with use of Afrezza, this post is misleading with respect to the drug's safety. We note the inclusion of the statement, "Please see full Prescribing Information, including boxed WARNING, Medication Guide, and Instructions for Use" with a link to the PI in the post. However, this statement does not mitigate the misleading impression from the claims in the post.

We also note that information regarding the risk of acute bronchospasm in patients with chronic lung disease appears together with Afrezza's indication in text format in a separate pop-up box that is visible when hovering a cursor over the thumbnail of the Afrezza logo in the top left corner of the post. However, presenting risk information for Afrezza in this manner does not mitigate the misleading impression from the claims in the post. Moreover, neither the post nor the pop-up box include information regarding two of the conditions for which Afrezza is contraindicated (i.e., during episodes of hypoglycemia and in patients with hypersensitivity to regular human insulin or any of the Afrezza excipients) nor any of the other warnings and precautions associated with the drug. This is especially problematic from a public health perspective given the multiple serious and potentially life-threatening risks associated with the drug.

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mannkind-corporation-578282-10052018

Warning Letter – Zarbee's, Inc.

- July 27, 2014
- Dietary supplement mfg.
- FDA pointed out the following as evidence that the products were misbranded:
  - Company social media (Facebook and Twitter) posts; and
  - Consumer testimonials posted to company Facebook

Warning Letter – Zarbee's, Inc.

June 27, 2014

WARNING LETTER

VIA UPS Overnight

Mr. Bryce L. Johnson, Owner
Zarbee's, Inc.
11650 S State St., Ste. 101
Draper, UT 84020-7144

Ref: DEN-14-09-WL

Dear Mr. Johnson:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.zarbees.com in May 2014 and has determined that you take orders there for the products "Zarbee's Naturals Children's Cough Syrup+Mucus Relief," "Zarbee's Naturals Children's Cough Syrup," "Zarbee's Naturals Children's Cough Syrup Nighttime," "Zarbee's Naturals Seasonal Relief," "Zarbee's Naturals Sleep," and "Zarbee's Naturals Children's Sleep,"which the website promotes for conditions that cause the products to be drugs 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 therapeutic claims on your website establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/zarbees-inc-429329-06272014

Warning Letter – Zarbee's, Inc.

Twitter & Facebook content

In addition, claims on your Twitter page, https://mobile.twitter.com/ZarBees, which has a link to your website at http://www.zarbees.com where products can be purchased directly, provide further evidence that your products are intended for use as drugs:

- **On February 7, 2014: "Try @Zarbees #naturalremedies for Cold and Cough Season..."**
- **On January 30, 2014: "RT@MomCentral Have you tried #ZarbeesCough for cold and cough relief?"**

Further, claims made on your Facebook page https://www.facebook.com/ZarBees, which also has a link to your website at http://www.zarbees.com where products can be purchased directly, provide additional evidence that your products are intended for use as drugs:

Posts by your company on your Facebook page include the following:

- On February 12, 2014: "Natural Ivy Leaf extract...helps thin and loosen wet mucus coughs...[u]sed in our Children's Cough Syrup +Mucus Relief..."
- On February 6, 2014: "Dark honey[an ingredient used in "Zarbee's Naturals Children's Cough Syrup+Mucus Relief" and "Zarbee's Naturals Children's Cough Syrup"]...is clinically proven to calm coughs and sore throats in children...".

Warning Letter – Zarbee's, Inc.

Facebook likes and comments

Your Facebook page also contains evidence of intended use in the form of personal testimonials recommending or describing the use of products for the cure, mitigation, treatment, or prevention of disease. Examples of such testimonials, which are endorsed or promoted by Zarbees, **include:**

- Zarbees "liked" the following comment made on October 15, 2013: "Received the sample for allergy relief and my husband had a terrible problem with allergies…he was very impressed on how well it worked for him…"

- On February 4, 2014: "…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…"
  - On February 4, 2014: Zarbees commented "Mary, Thank you for writing this!!! We love to hear that we have helped people…" on this claim.

- On January 6, 2014: "…It is the best thing for my granddaughters bronchitis."
  - On January 7, 2014: Zarbees commented "Vivian, we switched that item out with our Children's Nighttime Cough Syrup which works great!!!" on this claim.

- Zarbees "liked" the following comment made on February 11, 2014: "…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…"

- Zarbees "liked" the following comment made on January 7, 2014: "I've been battling either bronchitis or pneumonia for the last 18 days and have tried everything…your Children's Cough Syrup and mucus relief got rid of…my hoarsness [sic]…[m]y throat and chest are beginning to feel so much better…"

- Zarbees "liked" the following comment made on October 30, 2013: "Love Zarbee's this is the only medicine we use for our 2 year old. Colds and congestion clear up in 2 days."

Warning Letter – NanoBiotech Pharma

- February 26, 2015
- Dietary Supplement mfg.
- FDA used the following as evidence of intended use:
  - Patient testimonials on company website;
  - Posts made on company social media pages (Facebook and LinkedIn); and
  - Metatags used to bring customers to the company website
- Metatags were not primary issue of concern but supplemented evidence of intended use and misbranding

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/nanobiotech-pharma-446481-02262015

NanoBiotech Pharma – Warning Letter

WARNING LETTER

VIA EXPRESS MAIL

Gary S. Mezo
NanoBiotech Pharma, Inc.
7512 Dr. Phillips Blvd.
Suite 50-240
Orlando, FL 32819

7932 West Sand Lake Road
Suite 106
Orlando, FL 32819

RE: 446481

Dear Mr. Mezo,

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your websites at the Internet addresses http://www.nanobiotech.us, http://www.nanobiotech.squarespace.com, and http://www.nanobiotechpharma.com in December 2014 and has determined that you take orders there for the products NanobacTX and Urobac, which the websites promote for conditions that cause them to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your websites establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You may find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

NanoBiotech Pharma – Warning Letter

Website content

Your websites also contain evidence of intended use in the form of personal testimonials recommending or describing the use of NanobacTX and Urobac for the cure, mitigation, treatment, or prevention of disease. Examples of such testimonials include:

Under the "Testimonials" tab:

- "Nanobiotech's researchers have performed a pilot study of 91 patients using NanobacTX for three months: Of the 91 participating patients, the mean decrease in their coronary artery calcification scores was 58.5% after treatment with NanobacTX for three months. Interestingly, in 19 of those 91 patients 100 percent of coronary artery calcification was eradicated."
- "NanobacTX could probably replace half the stent, bypasses and heart surgeries taking place..."
- "Prior to his treatment, he had a HeartScan calcium score of 343 ... We treated him with NanobacTX and the follow up score was ... 26 ... Again he is angina free and had his cardiac meds reduced by approximately 2/3rds."
- "On continuing the NanobacTX treatment my peripheral neuropathy went away and my cardiac arrhythmia totally resolved!"

NanoBiotech Pharma – Warning Letter

Facebook page content

In addition, claims for NanobacTX and Urobac made on your Facebook page, https://www.facebook.com/NanobiotechPharma, which has a link to your website at http://www.NanoBiotechPharma.com, where the products can be purchased directly, provide further evidence that these products are intended for use as drugs:

- On December 4, 2014: "[Y]ou cannot have a heart attack if you do not have coronary artery plaque. NanobacTX reverses the plaque volume."
- On December 2, 2014: "REVERSING CORONARY ARTERY DISEASE CAN BE DONE .... The agent that caused reversal of calcified CAD plaque & Anginal symptoms? NanobacTX...."
- On October 24, 2014: "NanobacTX ... Lower CAC score, Eliminate & reverse coronary artery plaque ... & eliminate angina."
- On October 8, 2014: "Atherosclerosis and the underlying pathologies can be reversed with NanobacTX..."
- On September 16, 2014: "Vascular Dementia and symptoms can be reversed as well as Atherosclerosis of the brain. ...We have clinical trials planned in Vascular Dementia & Alzheimer's with our non-prescription NanobacTX."
- On June 11, 2014: "Use NanobacTX for 6-12 months until symptoms/presence of AD [Alzheimer's Disease]/Dementia subside or are eradicated... Vascular Dementia & Alzheimer's Disease. Our hypothesis is that NanobacTX either rescues cognition, or prevents further decline."
- On October 15, 2013: "Many scholarly articles connect the persistent state of inflammation with chronic diseases such as cancer, heart disease, Lyme, Fibromyalgia...[I]nflammation can be stopped and reversed with our Nanobiotics: NanobacTX, Urobac..."
- On August 28, 2013: "Our Urobac is shown ... to eliminate ... the calcification, biofilm and inflammation in the prostate that cause BPH."

NanoBiotech Pharma – Warning Letter

LinkedIn page content

Moreover, claims for NanobacTX and Urobac made on your LinkedIn page, https://www.linkedin.com/company/nanobiotech-pharma, which also has a link to your website at http://www.NanoBiotechPharma.com, where the products can be purchased directly, provide additional evidence that these products are intended for use as drugs:

- "NanobacTX ... shown in published clinical trials by cardiologists & radiologists to 1) regress Coronary Artery Disease Plaque ... 2) to Stop Angina Chest Pain..."
- "Urobac for Kidney Stones, PKD, Chronic Prostatitis & BPH."

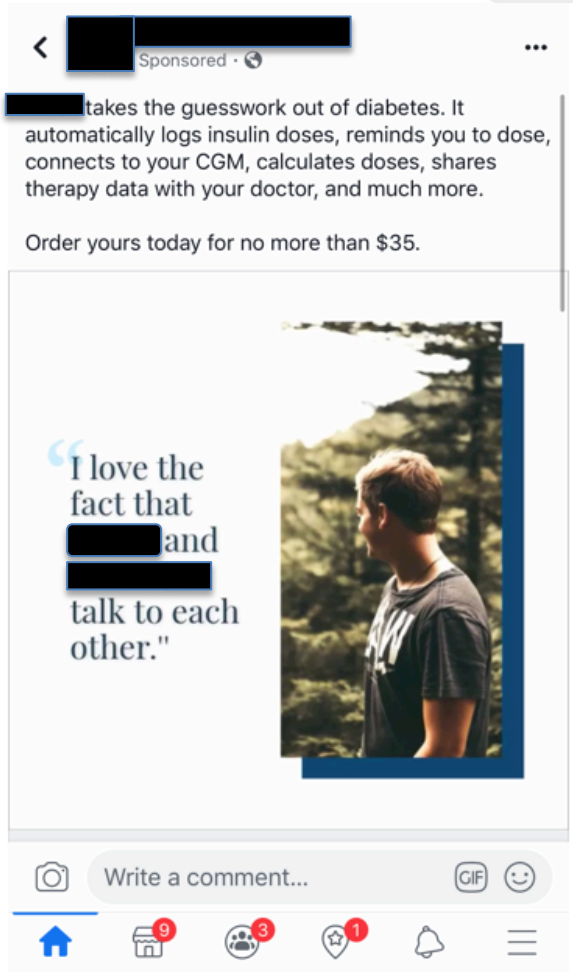
NanoBiotech Pharma – Warning Letter

Metatags

These reference citations and other claims quoted above are supplemented by metatags used to bring consumers to your websites through Internet searches. The metatags are "CAC," "CAD," "coronary artery disease," "has heart disease been cured," "Heart Disease," "Calcification," "chronic prostatitis," "kidney stones," "glaucoma," "amd" [age-related macular degeneration], "bph" [benign prostatic hyperplasia], "IC," "interstitial cystitis," "cataracts," "ED" [erectile dysfunction].

More Real World Examples

Is there enough risk information disclosed? What should be added?



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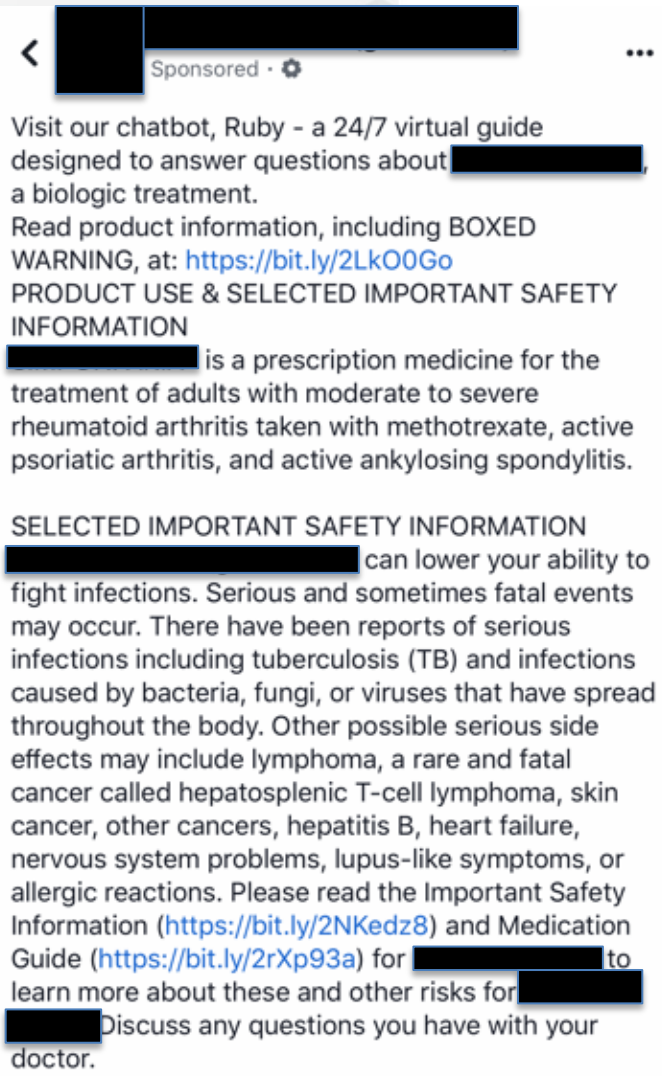
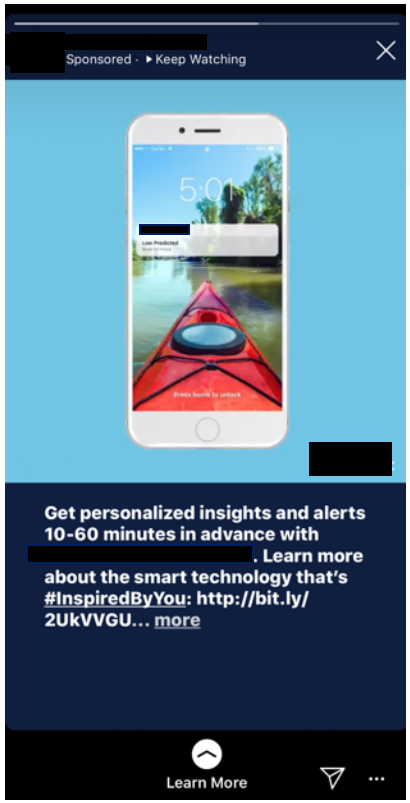
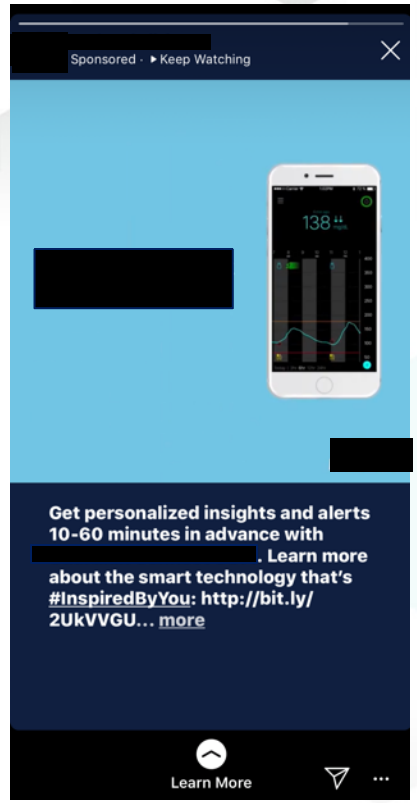
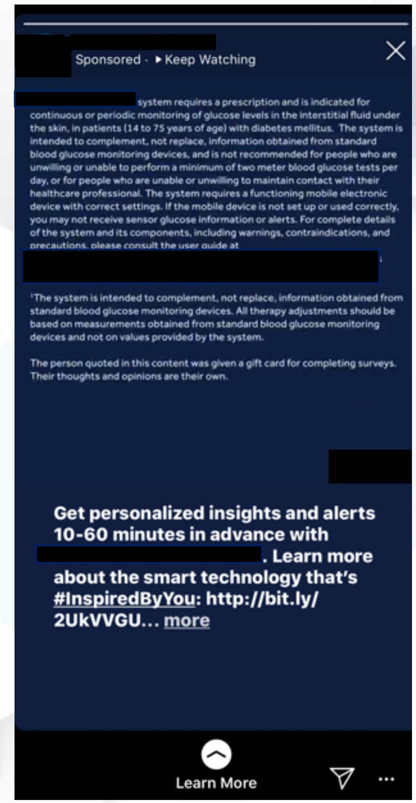
Methods of Disclosing Risk Information



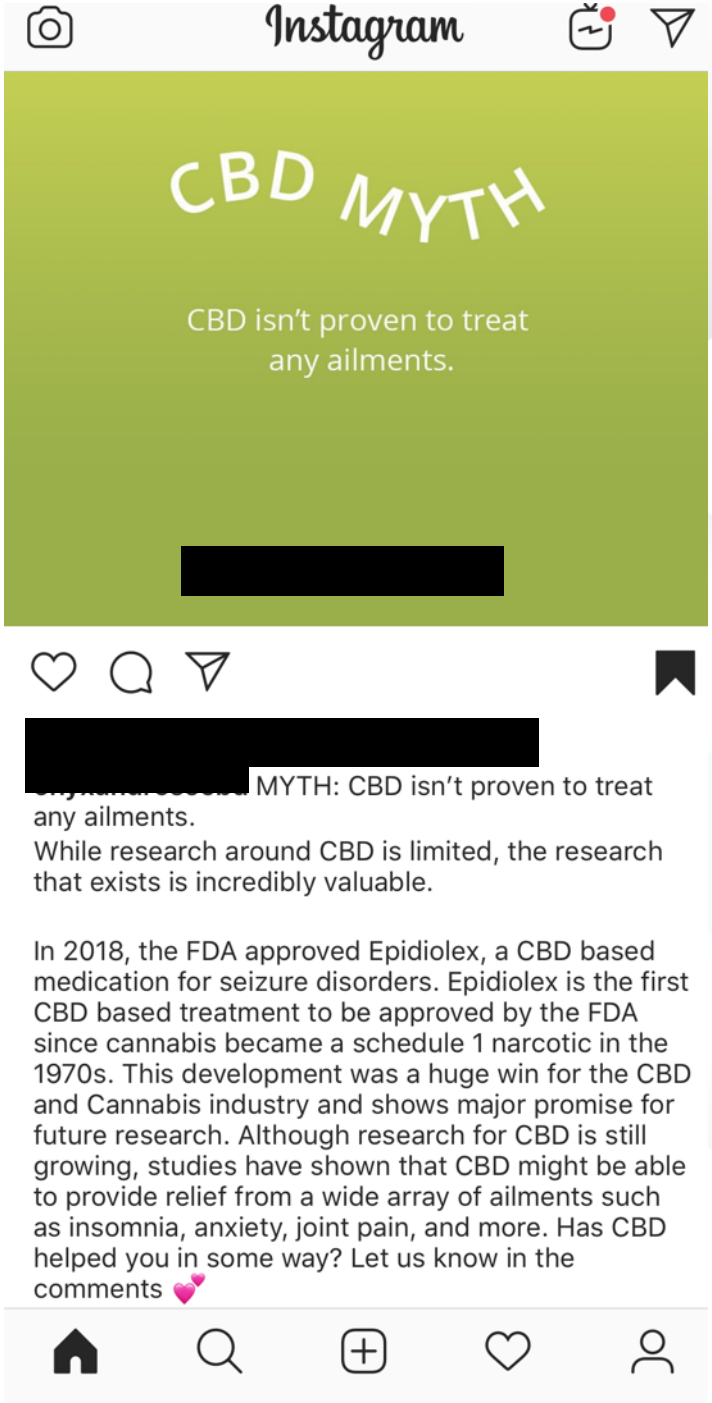
Methods of Disclosing Risk Information:







Misbranding:



Customer testimonials reposted by Company:

Recently being diagnosed with PCOS was the hardest struggle for me. I am NOT overweight (I am 5'5 weighing 130) but I did show multiple follicles in my ovaries with insulin resistance. I thought it was the end of the world, I was breaking out uncontrollably, my hormones were EVERYWHERE and thanks to you and your amazing product I am thankful to say I now have restored my period, I have CLEAR GLOWING SKIN and finally after months I am OVULATING! I cannot thank you enough for coming up with such an amazing product and thank you for making it so affordable. I will continue to buy this product and support this brand!!! ❤️❤️❤️❤️

[redacted] review regarding PCOS and insulin resistance

Balance review regarding post-partum, c[redacted]n, PMS symptoms and hair health!

I know you get these every day, but I know how important it is as a business owner to constantly see your products success! I have been taking Balance for a month now and HC[redacted]. I have suffered from a lot of postpartum hormonal issues since having my second child. My hair has never stopped falling out and breaking, my skin has been horrible despite never struggling with breakouts EVER before, my period has been a two week ordeal of extreme nausea and cramps and mood swings to the point I swear I have to be pregnant every month because it is so extreme. I watched success stories with balance for a few months before finally deciding to grab some myself. I'm so busy that I wasn't really watching for changes until I started getting a ton of comments that my hair looked absolutely beautiful and my skin was glowing. My mom even asked if I was hiding something because my skin was BEAMING! 😂.

I realized my hair had not been breaking at all, it was so shiny and full instead of dull. I had not had a breakout and the redness in my skin was almost completely gone AND I have been sleeping like a baby. I was waiting for my time of the month to see how my body would react and now I am officially blown away. I didn't even know my period was coming because my usual cramps and extreme nausea the week before didn't show up! I also haven't even had A SINGLE CRAMP since it started . Coming from someone who is usually on the couch in pain the whole time... could cry! I have struggled so badly with postpartum depression and postpartum hormone issues and it was to the point I assumed i would stay that way forever. I cannot even begin to thank you enough for the obvious time and effort put into this product. It has changed so much for me and I am so incredibly grateful.

[redacted] is safe and can be beneficial to take post-partum. However, we always recommend consulting your doctor before taking if nursing!

My husband and I struggled for 14 months to conceive! We had 2 miscarriages in between I could only imagine how badly my hormones were imbalanced. I was super skeptical in buying Balance because it felt like every tried nothing worked.. my skin was so bad from my hormones acting crazy too.. another thing is I had the worst anxiety after these miscarriages, it was so bad that it would feel like I'm under water and I was struggling to catch my breath.. I didn't want to get out of bed, and I was a miserable person to be around.. I wasn't myself for what felt like forever!

I can honestly say after my first month of [redacted], my skin was looking better, I was a lot happier, and I actually had a regular period with OVULATION!! Apparently I wasn't ovulating properly.

I am in my 2nd week of my 2nd bottle and I am so happy to say that we are finally expecting our RAINBOW 🌈 !! And It wouldn't have been possible without your product!

[redacted]e regarding fertility, ovulation & anxiety

This client has suffered with cystic acne, black heads and white heads from a young age. Spironolactone didn't help.

Results are from three weeks o[redacted] and she also reported that her mood and sleep schedule has improved as well 🧡

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Distilling it Down

Best Practices

- Implement a social media SOP/policy
  - Company personnel expectations
  - Methods for planning, creating, launching, & tracking social media programs/campaigns
  - When correction of misinformation can be considered
- Plan for content/posts
  - Consider appropriate platform(s) for presentation
  - Content reviewed and approved by the PRC/MLR/LRC/etc. committee
  - Submit to OPDP (drug only)
- Have a plan for responding to DM's or comments
  - Canned responses should be proactively created
  - Who is responsible for responding to DMs or comments

Best Practices

- Balance benefit information with risk information
  - Consider the cleared/approved indication (including patient population), contraindications, warnings, and precautions
  - If there is not enough space to communicate the required benefit and risk information in a single post, then the platform should not be used for that message.
- Monitor the social media program
  - Compliance with company's SOP and community guidelines (e.g., no hateful speech)
  - Monitoring for misinformation, off-label questions, complaints, risk information, platform changes

Social Media Takeaways

- Social media extends to more than just ”typical” social media platforms
- Use of social media for advertising will continue and evolve
- Consider third party vendors, privacy implications to data collection, etc.
- Monitoring social media is a key element to a healthy social media program
- FDA, FTC, and OIG, plaintiff’s lawyers, competitors, and other unfriendly parties look at statements made on social media
- Statements made on social media may be considered labeling and/or advertising and may be used to determine the intended use of your product

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Attend our CLE program on new EU and US regulations

Register here:
http://events.r20.constantcontact.com/register/event?oeidk=a07egm4z04d251f68cf&llr=kra7hp5ab

Learn about new laws and regulations from European and US regulatory lawyers.

Topics include: MDR, Transparency, GDPR, Compliance and more.

Thursday, November 7th, 2019, 8:00 a.m. – 1:00 p.m.

The Depot, Renaissance Hotel, 225 3rd Ave S, Minneapolis, Minnesota
Remote option also available.

This is a complimentary event.

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Agenda:

8:00 a.m. – 8:30 a.m.
Registration – *Breakfast provided.*

8:30 a.m. – 9:30 a.m.
General Data Protection Regulation (GDPR).
Topics include: controller/processor concept, subject access requests, data breaches, international data transfers, clinical trials, enforcement trends.
Speaker: Oliver Süme, Partner, Technology, Outsourcing and Privacy, Fieldfisher

9:30 a.m. – 10:15 a.m.
EU Medical Device Regulation (MDR).
Topics include: New obligations, responsible person(s), notified body concerns, MDD vs. MDR.
Speakers: Dr. Cord Willhöft, LL.M., Partner, Life Sciences, Fieldfisher
and Jim Murray, M.Sc., Consultant, Gardner Law

10:15 a.m. – 10:30 a.m.
Break

10:30 a.m. – 11:00 a.m.
EU Health Care Compliance.
Topics include: MedTech Europe Code of Ethical Business Practice, health care compliance in the EU and Germany, transparency.
Speaker: Dr. Cord Willhöft, LL.M., Partner, Life Sciences, Fieldfisher

11:00 a.m. – 12:00 p.m.
US Health Care Compliance.
Topics include: 2020 AdvaMed revisions, transparency reporting changes, compliance program auditing and monitoring, recent cases.
Speakers: Mark Gardner, M.B.A., J.D., President, Gardner Law
and Amanda Johnston, J.D., R.A.C., Sr. Attorney, Gardner Law

12:00 p.m. – 1:00 p.m.
Panel Discussion – *Lunch provided.*
Speakers from the morning convene for a moderated panel discussion with audience participation. Come equipped with your questions.
Moderated by Heather Potter, J.D., Associate Attorney, Gardner Law

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Questions?

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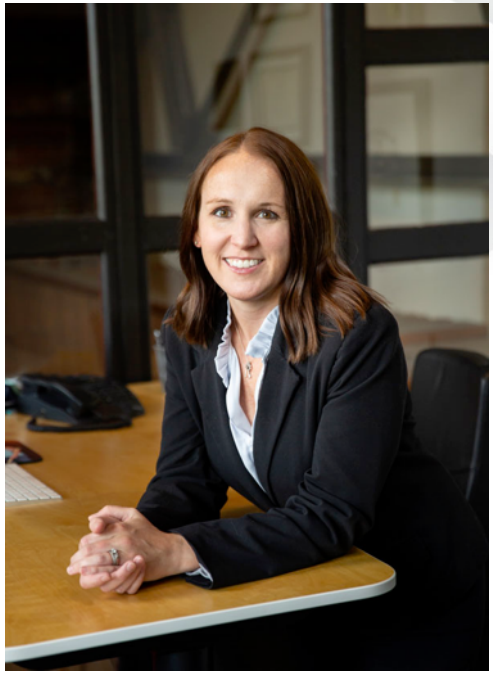

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