Key Takeaways From FDA's Latest Social Media Warnings

By **Dominick DiSabatino, Cortney Inman and Julian Klein** (December 3, 2024)

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On Oct. 31, the U.S. Food and Drug Administration's Office of Prescription Drug Promotion posted an untitled letter taking issue with Merz Pharmaceuticals GmbH's social media promotion of Xeomin, an injection for intramuscular or intraglandular use.[1]

This marks the OPDP's fifth untitled letter of the year, and the second relating to social media promotion of a product.[2]

The agency yet again hammers "consistent with label," or CFL, issues, but also did something curious and a bit more nuanced in terms of safety presentation, treating a run-of-the-mill social post more like a television commercial than what industry has become accustomed to over the years in short-form media promotion.

This article will summarize the letter and present three major takeaways relating to risk presentation, FDA labeling requirements and superiority claims.

Xeomin is indicated for "the temporary improvement in the appearance of moderate to severe glabellar lines," and carries a number of serious risks, including a boxed warning.

The promotional content at issue — a short-form video Instagram reel — appeared on the Xeomin Aesthetics Instagram account as well as the personal Instagram account of Nate Berkus, under a "[p]aid partnership with xeominaesthetic."[3]

In the letter, the FDA highlighted three issues.

Misleading Risk Presentation

The FDA flagged the presentation of risk information, including side effects and contraindications associated with the drug, which the FDA found was not presented in a manner commensurate with the benefit claims.

The FDA noted that the reel "includes an attention-grabbing presentation of Nate Berkus dancing to music as he is getting 'ready for a big night out,' during which, Berkus states that Xeomin is a 'smart tox,' and that it 'smoothes the look of frown lines' and further implies that it will keep him 'looking fresh.'"

Throughout the 40 seconds of video, the indication and use statement for Xeomin is displayed as static, onscreen text.

However, the consumer's first introduction to risk information comes at the end, "after approximately three seconds of a black screen with no audio."

As a result, the FDA unsurprisingly concluded that this risk information appeared with comparably less prominence than the attention-grabbing visual story of the drug's benefits.

Further troubling for the FDA was the fact that the risk information was displayed using fast-paced text that was difficult to read.

Further, while the caption of the post included limited risk information, this was insufficient to "mitigate the post's overall misleading minimization of risk," according to the FDA.

Ultimately, although there is actually very little said about the drug and its benefits in the post, the FDA concluded that the post was misleading and "fail[ed] to present [risk] information ... with a prominence and readability reasonably comparable with the presentation of information relating to benefits of the drug."

Misleading Efficacy Presentation

The FDA also took issue with the substantive information included in the post. First, the FDA was concerned with the misleading impression created by the following presentations and claims:

- Alongside "scenes of Nate Berkus's preparation routine and eventual departure for an event," Nate states in a voice-over: "Keeping my dermatologist on speed dial is my secret weapon for looking fresh. You never know when those lines might decide to make a surprise appearance. That's why she recommended Xeomin ... that smooths the look of frown lines."

- The caption includes the statement, "My pro-tips for getting ready for a night out; tuxedo at the ready, fries and Xeomin (incobotulinumtoxinA) @xeominaesthetic for smoothing my frown lines."

The FDA found that the promotional reel and caption misleadingly suggested that Xeomin can provide rapid results for smoothing frown lines in preparation for a same-day event, which, according to the agency, is not supported by efficacy data for the drug.

The FDA noted that the efficacy of Xeomin was based on a composite endpoint that compared effects on day 30 of the trial, and that composite endpoint treatment success was not evaluated before Day 7. Thus, the FDA found that there was insufficient evidence to support the fast-acting or same-day onset claims suggested by the post.

Second, the FDA also concluded that the following statements misleadingly implied that Xeomin is superior to other comparable products:

- Xeomin is "a double-filtered smart tox that smooths the look of frown lines with only the ingredients that you need for treatment"; and

- The hashtag, "#SmartTox."

The FDA concluded that these claims misleadingly suggest that due to its manufacturing process and formulation, Xeomin offers benefits over other botulinum toxin products, when this has not been demonstrated[,]" despite a description section of the prescribing information that states the formulation is "without accessory proteins[.]"

Although not expressly stated, the FDA's reasoning and conclusion suggest that, taken as a

whole, this presentation constituted an implied superiority claim that was unsubstantiated by head-to-head studies.

Takeaways

At first glance, some of the OPDP's findings in this letter seem like head-scratchers.

Failure to adequately communicate risk information is and always has been low-hanging fruit for the agency, but here there was safety information both in the video and in the post text — albeit relegated to a fast-moving scroll at the end of the video and a click-through on the post caption.

At least Merz attempted to include risk information for Xeomin, unlike previous untitled letters.[4] So, what gives? When analyzing the letter as a whole, a few nuances stand out as noteworthy and potentially indicative of new and continuing agency focuses.

First, and most importantly, the FDA's concerns relating to the presentation of safety information may suggest a shift in what the agency considers acceptable for the presentation of benefit-risk information in short-form video content.

Historically, it has been common in the industry to place safety information at the end of this type of short-form social media content. Merz's advertisement generally aligns with this traditional approach; however, the FDA's disapproval of the Xeomin Instagram reel signals that, at least in some instances, this practice may be problematic.

Indeed, on closer inspection, a few buzzwords stood out in the letter, prompting us to revisit an older 2009 draft guidance on presenting risk information in prescription drug and medical device promotion.[5]

In this guidance, the FDA provides a framework of considerations relating to the content and formatting of promotional materials. For example, among other things, this guidance warns that:

- "FDA looks not just at the specific risk-related statements" in isolation, "but at the net impression";[6]
- Signals should be "consistent across benefit and risk information" and "[p]resenting risk information with no signal ... can also minimize the risks of the product and mislead audiences";[7] and
- The organization of information presented in a piece plays an important role in consumer comprehension and recall, and thus "risk information should ... appear as an integral part of the piece."[8]

The FDA states that "the overall effect of this presentation undermines the communication of important risk information," noting that "the reel does not present any signal to alert the viewer that important risk information is presented after" Nate Berkus says goodbye.

Moreover, because the risk information was presented solely at the tail end of both the reel and caption, this information was "unlikely to draw the viewer's attention."

It is worthwhile to note that the first substantive comment the FDA makes in the letter

about the video relates to dancing. Those who have followed the OPDP over the years will appreciate the agency's apparent disdain for dancing.[9] It is safe to say, now, that dancing visuals are a de facto attention grabber and should trigger an automatic reevaluation of the safety presentation.

Perhaps the FDA may have felt differently if Merz had included superimposed text throughout or if Berkus had signaled to viewers to stick around for the safety information.

Nonetheless, manufacturers may need to reevaluate methods for incorporating risk and safety information in short-form social media content.

This is especially true given that, as of Nov. 20, the FDA's final rule concerning direct-to-consumer prescription drug advertisements is now fully in effect.[10] The OPDP is likely to keep an even closer eye on direct-to-consumer advertising, and some of the principles from the final rule, including its focus on consumer perception, may cross over to social media as well.

Second, as with most recent OPDP letters, this letter further cements the continuing importance of the FDA's CFL guidance.[11]

This letter draws some comparisons to the FDA's letter to AbbVie Inc. earlier this year, wherein the FDA appeared to find a misalignment between the onset of action suggested by the promotional communication, and what was supported by the clinical studies section of the prescribing information.[12]

Merz's post may even be a more dramatic example, especially given that, unlike AbbVie's drug, which had an onset of two hours, Xeomin was not even tested for efficacy before the seven-day mark of the trial.

Unlike AbbVie's letter, the FDA did not directly reference the clinical studies section of Xeomin's prescribing information.

On the one hand, this may have been a minor oversight given that the studies described in the letter broadly align with the efficacy information included in Xeomin's prescribing information.

On the other hand, this omission could also signal that the FDA is keeping the door open for efficacy claims relating to the onset of action on a CFL basis.

Nonetheless, given that this is the second time this year that the FDA has discussed the onset of action, companies should carefully consider how a consumer might interpret any timing-related elements included in direct-to-consumer advertisements, and ensure that any such interpretations are adequately substantiated or disclaimed using appropriate context and audience-specific language.

Third, the FDA curiously found a superiority claim by the post highlighting a feature about the product, contained in the prescribing information, that deals with product formulation.

Merz promotes its double-filtered manufacturing process, which, according to the FDA, implies unique benefits for treating frown lines, a claim not supported by comparative studies.

Despite Xeomin's distinct formulation without accessory proteins, the FDA underscored that

it does not recognize any proven advantages over other similar FDA-approved treatments for moderate to severe glabellar lines.

One might argue this negative inference is a bit unfair, because Merz is merely highlighting features of the product that are also set forth in the FDA-approved labeling. Reasonable minds could differ on the robustness of a logic jump from feature highlight to superiority claim.

Of course, the FDA noted that this is not the first time the agency has communicated with Merz about its promotional content. Although this part of the letter is redacted, historically, such prior correspondences typically serve as additional motivating factors behind the OPDP untitled letter issuance.

Pairing this with any of the above-mentioned issues — especially the superiority claim — would shed much more light on the agency's rationale for admonishment here.

In sum, this letter reinforces the CFL agenda but more importantly underscores the need to revisit safety balance in short-form social content promotion.

The FDA's recent and ongoing research into consumer perception may be shaping a new approach to social media advertising, one that requires safety information to be integrated throughout in a meaningful and intentional manner.

The letter also underscores the importance of providing context to claims made about the onset of action — whether it be citing to the label or providing additional supporting data.

Finally, prior interactions with the FDA, especially if they have provided opinions or guidance, indicate a heightened risk level that should be carefully considered in communications and strategy.

The agency is a bit of a moving target when it comes to enforcement, but CFL and safety are good guideposts to aim for when reviewing promotional materials.

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[1] Untitled Letter available here: https://www.fda.gov/media/183512/download?attachment.

[2] FDA Law Update available here: https://www.fdalawblog.com/2024/07/articles/fda/fdas-second-untitled-letter-of-the-year-an-apparently-tough-choice-between-raising-awareness-and-public-safety-for-anaphylaxis-drugs/.

[3] Promotional Material available here: https://www.fda.gov/media/183513/download?attachment.

[4] See, e.g., FDA's Office of Prescription Drug Promotion Issues Second Untitled Letter of the Year to Exeltis for Misleading Statements Relating to SLYND® | FDA Law Update.

[5] Available here: https://www.fda.gov/media/76269/download.

[6] Id. at 4.

[7] Id. at 7-8.

[8] See id. at 9-10.

[9] See e.g., 2019 OPDP Untitled Letter to CooperSurgical; 2016 OPDP Untitled Letter to Sanofi-aventis.

[10] CCN Final Rule available here: https://www.federalregister.gov/documents/2023/11/21/2023-25428/direct-to-consumer-prescription-drug-advertisements-presentation-of-the-major-statement-in-a-clear?utm_medium=email&utm_source=govdelivery.

[11] Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers Guidance for Industry.

[12] FDA Law Update coverage available here: https://www.fdalawblog.com/2024/09/articles/untitled-letter/ubrelvy-untitled-letter-a-double-fault-for-abbvie-or-makeup-misread-for-fda/.