FDA Says Viewers Catch a Fleeting Glimpse; Can't Hear What You're Saying to Sponsor of Ad with Mismatched Audio and Visual Risk Information

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Recently, FDA's Office of Prescription Drug Promotion (OPDP) issued its first Untitled Letter of the year, citing a direct-to-consumer TV advertisement for a prescription weight- loss drug.[1] According to OPDP, the ad made false or misleading representations about the risks associated with the drug, thus misbranding the product. Notably, although the ad provided safety information about the drug, the agency took issue with the way this information was presented.

The Drug Product's Indication and Risk Information

FDA's letter summarizes the serious risks associated with the drug product, which is indicated for use as an adjunct weight-loss therapy for specific populations. The product's FDA-approved product labeling lists two limitations of use and contains boxed warnings regarding suicidal thoughts and behaviors and neuropsychiatric reactions, along with a number of contraindications.

Presentation of Risk Information

In assessing whether promotional materials are false or misleading with respect to risk, FDA looks at "not only representations made or suggested in promotional materials, but also failure to reveal facts that are material in light of 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."[2] In other words, omitting safety information can render otherwise truthful claims about a product misleading.

FDA's letter explains the two primary ways in which the ad was misleading and, thus, misbranded the product within the meaning of the Federal Food, Drug and Cosmetic Act (FD&C Act):

- First, the ad included efficacy claims, but failed to include important risk information.
  - The ad included the statement "Do not take with opioids," but did not include any of the other conditions for which the product is contraindicated.
  - Additionally, the TV ad included a statement that "[The drug] may increase suicidal thoughts or actions in some children, teens, and young adults within the first few months," but failed to disclose any information about neuropsychiatric reactions, which are also part of the boxed warning.

- Second, the ad communicated risk information in the visual portion of the ad only (i.e., as superscript), while at the same time presenting unrelated risk information in a competing audio message.
  - For example, the ad presented the warning and precaution for the potential risk of hypoglycemia in patients with type 2 diabetes only as a superscript. FDA asserts that this violates the regulatory requirement that "television advertisements shall include information relating to the major side effects and contraindications of the

1 https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm560127.htm (last visited June 16, 2017)
2 https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm560127.htm (last visited June 16, 2017)

advertised drugs in the audio or audio and visual parts of the presentation."[3]

- The ad also presented the contraindication for concomitant opioid use in the audio portion at the same time that it presented an unrelated superscript on the most common adverse reactions. This resulted in separate, unrelated risk information competing for consumers' attention.
- FDA states that "The overall effect of disclosing important risk information in SUPERs only, along with the simultaneous presentation of SUPERs and competing audio messages, undermines the communication of important risk information and thereby misleadingly minimizes the risks associated with the use of [the drug]."

AGG Observations

- FDA is continuing to make the point that the *manner*, not merely the *content*, of risk information is important. This letter echoes the message of the December 2016 Untitled Letter to another company, which cited "compelling and attention-grabbing visuals and SUPERs" which competed with consumers' attention during the presentation of risk information.[4]
- While the focus of that December 2016 letter was competing non-safety audio information, FDA has now taken issue with mixed safety messages—presenting two different risk information messages together can also be distracting to consumers.
- Presenting risk information solely in text format may not be sufficient to balance safety and efficacy claims. FDA will view the presentation as a whole.
- While this letter cites a television ad, companies should be cognizant of this latest commentary from FDA when developing any promotional video messaging.
- The issue here was not related to off-label promotion. FDA is still taking enforcement action against misleading information, particularly where there are safety concerns.

3 21 CFR 202.1(e)(1)

4 https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM533292.pdf (last accessed June 16, 2017)

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