OPDP Issues Untitled Letter: How NOT to Present Risk Information in a DTC TV Ad

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On July 25, 2019, the Food and Drug Administration's Office of Prescription Drug Promotion (OPDP) issued an Untitled Letter stating that a Direct-to-Consumer television advertisement (TV ad) made numerous false or misleading representations about the risks associated with a prescription drug product.[1] The TV ad included claims and representations about the indication and uses for the drug, but failed to include important risk information associated with the drug.

OPDP's Determination that the TV Ad is Misleading

The Untitled Letter includes OPDP's determination that the TV ad is misleading. OPDP highlighted the following aspects of the TV ad that created a misleading impression about the product:

- The TV ad includes a statement as an onscreen superimposed text (SUPER), "Don't use [product] if you have certain cancers[,]" but fails to include any other contraindications for the product (e.g., pelvic inflammatory disease).
- The TV ad includes an audio voiceover regarding calling a healthcare provider if the patient experiences certain symptoms, but fails to adequately communicate the material fact that the product is associated with an increased risk of pelvic inflammatory disease (PID) and that PID can have serious consequences. Moreover, the TV ad omits a warning for expulsion of the product.
- The TV ad communicates important risk information only in the visual portion of the ad via SUPERs, but not in the audio (or audio and visual parts) of the presentation.
  - Important risk information about the contraindications for certain cancers and the precaution for vaginal bleeding were only presented visually through SUPERs.
- The TV ad presents unrelated risk and benefit information in competing modalities that further minimizes the presentation of risk information (e.g., the TV ad discloses the contraindication for certain cancers in a SUPER simultaneously with audio about unrelated risk information to call a healthcare provider if experiencing certain symptoms; the TV ad discloses risk information about a precaution in a SUPER simultaneously with unrelated audio and visual benefit claims).

OPDP Determination Regarding "Major Statement" of Risks

OPDP also determined that the risk information presented in the "major statement" of risks through audio and SUPERs was undermined by simultaneous visual presentations. (e.g., fast-paced visuals that feature choreographed dancing to instrumental background music and multiple scene changes). OPDP determined that the "compelling and attention-grabbing visuals" were unrelated to the risk message presented in the audio and SUPERS, and compete for the viewer's attention. These visuals were also accompanied by frequent scene changes and other competing modalities (e.g., background music). Due to these features, OPDP determined that the TV ad created a misleading impression of the drug's risks because it was difficult for the viewer to adequately process and comprehend the risk information.

1 The Untitled Letter is available at the following link: https://www.fda.gov/media/129526/download.

OPDP also found that the TV ad included a number of claims and presentations that further minimized the risks associated with use of the product. The numerous statements that the product contains "No hormones!" or is "100% HORMONE FREE," created the misleading impression that the product does not have the potential negative health effects of hormone contraceptives, such as long-acting reversible contraceptives. Although it is true that the product is hormone-free, the "overwhelming repetitive nature' of these claims and the misleading omission and presentational elements of the TV ad previously discussed, created a misleading impression of the safety profile for the drug. This was particularly concerning to OPDP in light of the fact that there are potentially fatal risks associated with the product.

Company Action

The Untitled Letter requests that the company immediately cease violating the Federal Food, Drug, and Cosmetic Act, and submit a written response to OPDP to explain the company's plan to cease the violative conduct. The company may also submit its reasoning for why it believes that the products are not in violation of the FD&C Act and supporting information for the agency's consideration.

AGG Observations:

- FDA was made aware of the TV ad based on submission of Form FDA 2253 and the FDA Bad Ad Program
  - Health care providers, consumers, and competitors may be monitoring and could send a complaint.
- Supers are generally not sufficient to mitigate incomplete or misleading promotional statements or visual presentations regarding safety, efficacy, and typical course of treatment.
- The "major statement" of risk information in TV ads must include information relating to major side effects and contraindications in the audio or audio and visual parts of the presentation. See 21 CFR 202.1(e)(1).
- Unrelated risk and benefit information in competing modalities may minimize the presentation of risk information.
- Compelling and attention-grabbing visuals presented simultaneously with a SUPER or audio message may detract from the presentation of important risk information.
- Repeating a particular product attribute numerous times ("No hormones!"), although true, may minimize risk by suggesting a product does not have negative effects of competing products.
- t is important to include all contraindications and the most serious warnings from the approved labeling in all product promotion.

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