

FROM AN INSTAGRAM POST TO A TELEVISION COMMERCIAL, OPDP ISSUES ITS FOURTH UNTITLED LETTER OF 2024

In what has now become a common mash-up of celebrity influence and pharmaceutical marketing, a recent direct-to-consumer ("DTC") television advertisement ("TV Ad") came under fire from the Food and Drug Administration's ("FDA") Office of Prescription Drug Promotion ("OPDP" or "agency") in the agency's fourth **Untitled Letter** of the year. With only three months left in 2024, we are getting closer to matching the number of enforcement **letters** from 2023. The latest Untitled Letter takes issue with a pharmaceutical company's television commercial featuring tennis superstar and businesswoman Serena Williams for making misleading claims about their drug's efficacy in treating migraines.

OPDP highlights several concerning elements of the TV Ad that suggest the migraine treatment can deliver benefits beyond what has been clinically validated. In the TV Ad, Williams is depicted struggling with migraine symptoms—hand on her head, shielding her eyes from light—before transitioning to a scene where she walks confidently down a blue-lit path after taking the drug. OPDP found that this stark before-and-after portrayal, paired with Williams' voiceover stating, "One dose works fast to eliminate migraine pain," and the accompanying prominent graphic "[DRUG] QUICKLY ELEMİNATES MIGRAINE PAIN," misleadingly suggests that the drug eliminates migraine pain and symptoms quicker than what was demonstrated in the clinical trials.

The efficacy of the migraine treatment was evaluated in two separate clinical trials, based on two endpoints: 1) the effect of pain freedom at two hours post-dose (defined as a reduction of moderate to severe headache pain to no pain and 2) the effect on the most bothersome symptom ("MBS") (*i.e.*, phonophobia, photophobia, nausea) freedom at two hours post-dose compared to a placebo. In Study 1, 19.2% and 21.2% of patients on the drug (50 mg and 100 mg) achieved pain freedom, versus 11.8% on placebo, and 38.6% and 37.7% achieved MBS freedom compared to 27.8% on placebo. In Study 2, 21.8% of patients on the drug (50 mg) achieved pain freedom versus 14.3% on placebo, and 38.9% achieved MBS freedom versus 27.4% on placebo.

OPDP found that the TV Ad misleadingly implied that a single dose of the drug could quickly eliminate migraine pain, despite clinical trials showing that only about 19% to 22% of patients achieved pain relief within two hours of taking one dose of the drug. In fact, 78% to 81% of patients did not achieve pain freedom after receiving one dose of the treatment. This finding is unsurprising considering that the approved Prescribing Information for the drug states, "If needed, a second dose [of the drug] may be taken at least two hours after the initial dose." Moreover, OPDP acknowledged that the frame where the claims appear includes a small SUPER stating "some people had pain freedom within two hours," but found that the SUPER was "not sufficient to mitigate th[e] misleading suggestion that the drug can eliminate migraine pain and symptoms more quickly than had been demonstrated." As such, OPDP concluded that the claim that "one dose eliminate[s] migrate pain" was misleading.

In addition to misleading efficacy claims, OPDP specifically highlighted how the issues in the TV Ad were compounded by the portrayal of Williams as a credible source, which may lend undue weight to the TV Ad's claims. As such, by featuring a celebrity athlete, OPDP found that the TV Ad amplified its potential to mislead audiences about the drug's efficacy.

PRACTICAL TAKEAWAYS

1. Companies should ensure all promotional materials provide clear, accurate information about a drug's safety and efficacy, *i.e.*, "fair balance."
2. When featuring celebrities or social media influencers in promotional materials, companies should be mindful that OPDP will heavily scrutinize those campaigns given the power and reach of the celebrity/influencer. While this was not a social media advertisement, it is worth noting that **Serena Williams** currently has 17.3 million followers on Instagram.
3. The inclusion of a disclaimer in the TV Ad (*e.g.*, SUPER) may not be sufficient to mitigate the overall misleading impression created by an advertisement.
4. When evaluating an advertisement, OPDP will not only consider the words used, but also the visuals that accompany those words to

determine whether it is misleading.

5. Companies should be mindful of advisory comments received from OPDP on a particular issue. In this case, the previous application holder had received advisory comments from the agency in 2020. While OPDP acknowledged that a new company was now the application holder, it was concerned that the company “appeared to be promoting [the drug] using similar claims and presentations in a misleading manner” as they had previously addressed. When acquiring an existing product, it is imperative to review the history of the product, particularly when it is related to advertising campaigns for which the FDA had provided advisory comments in the past, and make sure that those comments are considered when preparing a new advertising campaign for the drug.

For more information on the advertising and promotion of drugs, biologics or medical devices, please contact:

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