School Might Be Out, But OPDP Enforcement is Still Active

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Two recent enforcement letters, issued by the Food and Drug Administration's Office of Prescription Drug Promotion, demonstrate that OPDP never closes, even if vacation may be starting for some.

Summary of Enforcement Letters

In one Untitled Letter, issued in May to a generic drug company, OPDP objected to a sales aid, because the company described the abbreviated new drug application (ANDA) product's efficacy but failed to communicate any risk information and omitted material facts. Thus, the generic drug product was misbranded.[1] In the specific case, the sales aid included the indications and usage and product category, but it did not include any risks. OPDP expressed particular concern, because the ANDA product's prescribing information contained a Boxed Warning. The sales aid also failed to include the entire indication, which noted that the product was not a cure for the medical condition at issue.

In the second OPDP Untitled Letter, issued in June, the company objected to an NDA product website that omitted risk information, included unsubstantiated efficacy claims, and failed to disclose material facts.[2] As a result, the website misbranded the product.

OPDP noted that the website included a number of efficacy claims but omitted all (FDA emphasized) of the product's contraindications and adverse reactions. The agency acknowledged the website provided some risk information but not enough. While the website included a "Click here for full Prescribing Information," this did "not mitigate the misleading omission of risk information."

OPDP also objected to certain images that it believed made unsubstantiated efficacy claims. While the product was indicated as a short-term "adjunct in a regimen of weight reduction" based on a number of factors, the agency said references to "lean" were not supported by substantial evidence or substantial clinical experience, and "lean" was not associated with any clinical endpoints in the drug product's studies. In addition, the webpage did not include the FDA-approved indication in its entirety. It specifically omitted material facts that qualified, limited, or better identified for whom the product was intended.

AGG Observations

- Always include the indication in its entirety. Both enforcement letters cited the companies for omitting such material information. We recommend the indication be provided verbatim to minimize challenges of mischaracterizing the indication or even cherrypicking. However, at a minimum, we advise any modified wording include all of the relevant elements of the indication, good and bad (e.g., qualifiers or limitations), with review by the company's Promotional Review Committee.

1 The United Letter may be accessed at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM397400.pdf.
2 The Untitled Letter can be accessed at www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyFDA/warningletterandnoticeofviolationletterstostoppharmaceuticalcompanies/ucm400708.pdf.

- OPDP will issue enforcement letters to ANDA companies for unlawful promotion. Understandably, most enforcement letters are sent for NDA products, because of the typical differences in marketing approaches between innovator and generic companies. However, OPDP's enforcement authority is not limited to NDA products.

- As a reminder, the mention of an indication is a claim. While the indication may not be a "buy me" marketing claim, OPDP is clear that, once the indication is provided, fair balance, such as risk information, must follow. Furthermore, merely referring the user or reader to another place, such as a link, for more information, is inadequate.

- Particular attention should be paid to products with Black Box Warnings. While all products must comply with FDA's labeling requirements, those with Black Box Warnings typically receive more regulatory scrutiny.

- Companies must be careful about attempts to extrapolate the indication too far. For example, references to "lean" for a short-term adjunctive therapy, without substantial evidence or substantial clinical experience to substantiate, were found to be unlawful. We see many cases where clients want to make the perceived logical jump from A to B or think B is a subset of A but, without clinical data to support it, there is regulatory risk.

- The letter to the NDA holder copied the licensee of the product. While the OPDP does not describe the relationship, except as "agent," it appeared the licensee marketed the product, but the original addressee for the letter was the NDA holder. In OPDP's world, the NDA holder is ultimately responsible for regulatory compliance, although it will also copy an offending marketing partner in an enforcement letter.

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