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Client Alert

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DDMAC Strikes Again: Two More Enforcement Letters Issued to Drug Companies For Unlawful Product Promotion

Showing no signs of slowing down, Food and Drug Administration's (FDA's) Division of Drug Marketing, Advertising and Communications (DDMAC) issued two more enforcement letters to pharmaceutical companies for unlawful promotion. The Untitled Letter challenged a convention panel as misleading, because it broadened the approved drug product's indication and made unsubstantiated superiority claims. The Warning Letter cited another company's product-specific web pages for omitting risk information, not including important indication information, and promoting unapproved uses. The company also failed to submit the websites to DDMAC on Form 2253, as required by law. In the Warning Letter, DDMAC specifically cited public health concerns raised by broadening the product's indication or claiming safety when not demonstrated by substantial evidence or substantial clinical experience.

While the enforcement letters are publicly available, we will not identify the companies or specific products here.

In the case of the Untitled Letter, the company submitted a convention panel to DDMAC under Form 2253. While the product is approved for one use, the graphic suggested that it is approved for a broader range of conditions that had been demonstrated by substantial evidence or substantial clinical experience. The approved indication was limited, but this was not made clear (e.g., for use only as second-line therapy). DDMAC noted that the product was subsequently approved for first-line therapy, but this was not the approved indication when the graphic was first used and initially disseminated. In addition, DDMAC objected to the convention graphic claim that, because it lacked a particular ingredient, it was safer than a competitor. The agency said that the company provided no evidence to support such a superiority claim.

In the recently issued Warning Letter, DDMAC said that the product-specific web pages failed to provide risk information. While the company provided links to see the products' package inserts on the web pages, DDMAC found that the "these links do not mitigate the complete omission of risk information from the [... product] webpages." In addition, one product web page failed to include material limitations about the approved indication. In another product-specific web page, the company noted the product's approved use but also potential uses under development. DDMAC said the "presentation of both approved and unapproved product information for [... product] together in this manner is misleading because it implies that [... the product] is effective

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for unapproved uses." Similarly, a product-specific website included the FDA-approved indications, without limitations, but included at the bottom of the page the product's approved use in Europe, which was not approved in the United States. DDMAC expressed concern that the web page was intended for a US audience, but the approvals and limitations were different. As such, the web page statements misbranded the drug products. Finally, the FDA noted that the company failed to submit the web pages on Form 2253, as required, at the time of initial publication. The company must take corrective action.

These enforcement letters re-emphasize some points to consider with product promotion:

1. Companies must be careful not to jump the gun and promote a product that, while an application or supplement is pending, is not yet approved. That is, while the FDA ultimately approved the product for first-line therapy, the product's indication was different when the materials were first distributed.

2. Comparative claims, while tempting to distinguish products, must be carefully made. While a statement might be true in isolation, it can become misleading in context. For example, it is true that the product in the Untitled Letter lacked a particular ingredient, which a competitor product included. However, the claim that the absence of this ingredient made the product safer than the competitor was misleading, because it was not substantiated, according to the FDA.

3. DDMAC is reviewing more carefully websites and social media promotional forums. It is important that product-specific web pages clearly distinguish a product's regulatory status (e.g., approved versus investigational) and that the lines are not blurred to imply that an unapproved use is indeed approved. Similarly, companies must separate US-approved uses from ex-US-approved uses so that the regulatory approval status is not muddied, misleading or inaccurate.

4. DDMAC expects risk information and, more generally fair balance, to be presented at the same time when the indication or claims are made. It is not enough to provide the "good," but then direct the user to go somewhere else to see the "bad" (e.g., clicking on a link to see the full product information).

5. All web pages, websites, and social media venues used by companies to promote their products must be submitted to the DDMAC on a Form 2253 at the time of initial dissemination (for labeling) or initial publication (for advertising).

Review of Untitled Letters and Warning Letters provides insight into DDMAC's current thinking on promotional issues. It's better to review (others' mistakes) than to receive (enforcement letters).

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