Happy Holidays from FDA: The Agency Issues Four Enforcement Letters for Unlawful Promotion

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The Food and Drug Administration recently issued holiday gifts, in the form of enforcement letters, to four pharmaceutical companies. The letters are reminders that FDA is not in a partying mood when it comes to unlawful promotion.

The Office of Prescription Drug Promotion (OPDP) sent Untitled Letters to two prescription drug manufacturers for direct-to-consumer television advertisements that it alleged made "false or misleading misrepresentations" about the products' safety and risks.[1] The third letter, a Warning Letter, faulted a company for distributing a promotional e-mail to health care professionals that omitted risk information and contained misleading statements about the drug's benefits.[2] The fourth, also a Warning Letter, went to a company for a website that also misrepresented the product's safety, as well as did not provide the drug's full indication.[3] All four letters focused on the presentation of risk information.

While we will not discuss each letter in detail, as they are fact-specific, we will identify OPDP's major objections and note our observations.

In one television advertisement, the company provided risk information, but the visuals on the screen at the time included individuals smiling while engaging in various social situations. Additionally, text on the screen emphasized the scenarios with statements such as "YOUR **LIFE OF THE PARTY** IS SHOWING" (emphasis in original). In OPDP's opinion, the combination of the visuals, SUPER text on the screen, changing visuals and music minimized the risk. The letter noted that the combination of elements "compete for the consumers' attention . . . [a]s a result, it is difficult for consumers to adequately process and comprehend the risk information."

In another Untitled Letter, issued the same day, the agency used similar and, at times, verbatim language to express concern about another television advertisement's presentation of risk information:

> The presentation of these compelling and attention-grabbing visuals, all of which are unrelated to the risk message presented in the audio and on-screen SUPERS, in addition to the frequent scene changes and the other competing modalities such as the background music, compete for the consumers' attention. As a result, it is difficult for consumers to adequately process and comprehend the risk information. The overall effect undermines the communication of the important risk information and thereby misleadingly minimizes the risks associated with the use of [the drug].

In the Warning Letters, issued the day after the Untitled Letters, OPDP cited both companies for failing to communicate **any** (emphasized by the agency) risk information. In one of the letters,

1 See www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyFDA/warningletter-sandnoticeofviolationletterstopharmaceuticalcompanies/ucm533292.pdf;
See www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyFDA/warningletter-sandnoticeofviolationletterstopharmaceuticalcompanies/ucm533300.pdf.

2 See http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM533540.pdf.

3 See www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyFDA/warningletter-sandnoticeofviolationletterstopharmaceuticalcompanies/ucm533578.pdf.

the agency further objected to the company's promotional e-mail characterizing the drug as having "easy 30 mL dosing and delivery" without providing any information from the Prescribing Information regarding dosage and administration. In the second Warning Letter, OPDP found that there were superiority claims made about the product's safety, without supporting data. The company's website implied that the product, a tablet formulation, carried less risk of "dosing errors" than competitors in its class with liquid formulations. FDA pointed out that while the active ingredients differed, the Prescribing Information of both the company's product and its competitors include Black Box Warnings. The agency said:

> Comparing the safety profile of a single ingredient in a combination product to another single ingredient in a competitor combination product … is misleading as it fails to take into consideration the overall safety profile of the entire combination product.
>
> Such statements raise considerable public health concerns and are particularly alarming with respect to an opiate agonist product, as these controlled substances can lead to overdose, dependence, abuse, and death.

FDA also objected to the webpage because the company did not provide the approved indication in full – failing to disclose that the product contained a limitation of use regarding pediatric use. Finally, the company did not submit the webpage under Form FDA-2253. The agency requested that both companies distribute corrective messaging.

AGG Observations

- We have noted in a recent past Bulletin,[4] FDA will take enforcement action where it believes appropriate. While there remains some uncertainty about how the agency will address off-label promotion in light of court actions, we have reminded clients, and continue to emphasize, that FDA is not going away. All three enforcement letters focused on false or misleading communications and "misbranding." Off–label promotion was not cited.

- FDA has raised concerns in the past about DTC advertising and risk minimization. The issuance of the recent enforcement letters are reminders that companies must present a DTC advertisement in an objective, balanced manner, so that the risk information is not minimized by fanciful colors, music, or other imagery that distracts the consumer. Companies might consider conducting focus groups and developing consumer comprehension studies to evaluate the messaging before airing the promotion. It is beneficial to understand how a sample of consumers perceive the messaging in advance, because that is the lens FDA will use.

- We have seen FDA issue a number of enforcement letters to drug companies that omit a product's limitation of use. We remind clients that, if the approved indication includes a limitation of use, the company must provide this information in the promotion. It is not optional; it is mandatory.

- All three enforcement letters presented safety concerns. As noted, while the issue of FDA enforcement in the off-label promotional area is evolving, the agency will not sit idly by if it perceives messaging to present safety risks. DTC advertising only exacerbates that concern. A product with a Black Box Warning and with a high potential risk of abuse is a good candidate for a Warning Letter and corrective advertising.

- We remind companies, including those where we participate on the Promotional Review Committee, to remain vigilant in their review of promotional messaging. PRC members must continue to evaluate marketing pieces to ensure they are truthful and present risk information in an objective and balanced manner.

4 http://www.agg.com/What-a-Difference-a-Claim-Can-Make-FDA-Issues-a-Warning-Letter-for-Unlawful-Medical-Device-Promotion-10-20-2016/

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