Can You Hear Me? FDA Enforcement Actions Suggest Companies Better Listen

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Can you hear me? These four words from Mike + The Mechanics' 1985 hit song, *Silent Running*, come to mind when one reviews three enforcement letters issued by the Food and Drug Administration (FDA) in the last four months. One could envision the authors of the letters saying to themselves (and wanting to really write), "what part of no do you not understand?" While each enforcement letter is fact and product-specific and, therefore, not the focus of this Bulletin, the theme is the same - - don't ignore or underestimate FDA.

FDA Enforcement Actions

- In a July 25 Warning Letter issued to a pharmaceutical company, FDA's Office of Prescription Drug Promotion (OPDF) took exception to a local newspaper advertisement.[1] Clearly, OPDP was upset by the absence of any risk information in the ad, while the product's benefits were highlighted. However, also noteworthy, was OPDP's stated concern that the promotional activity was "particularly troubling" in light of a 2012 Untitled Letter for a video which, among other things, lacked emphasis on risk information. OPDP said in the 2013 Warning Letter that the drug company "is continuing to promote its prescription drug products in a violative manner." Lack of risk information + continued violations = Warning Letter.

- On the same day of that Warning Letter, OPDP released and posted an Untitled Letter to another drug company (the letter was issued two days before) for a detailing aid that minimized important risk information, overstated the drug's effectiveness, and omitted material facts about the product. OPDP objected to the aid for a number of reasons and noted that the company had ignored "repeated" concerns about product promotion. Indeed, the Untitled Letter referenced five sets of advisory comments from OPDP reviewers over a ten-year period addressing "similar misleading presentations" for the specific product.[2] The company "is continuing to promote … in a violative manner despite clear direction from OPDP."

- Finally, not to be outdone, FDA's Center for Devices and Radiological Health (CDRH) issued a Warning Letter in November to a medical device company.[3] While the subject matter of the Warning Letter is interesting because of some regulatory classification issues raised, the enforcement letter is almost humorous in its angry and perplexed tone. CDRH noted 14 face-to-face and phone meetings, "hundreds of email exchanges, and dozens of written communications" of guidance. The agency also sent a letter to the company in 2010, raising concerns about the product's lack of marketing authorization. A recently-aired national television commercial seems to have been the final straw for FDA. The result: the company must stop product sales until it obtains marketing authorization.

1 www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceutialCompanies/ucm363213.pdf.
2 www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm363215.pdf.
3 www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm376296.htm.

AGG Observations

1. Do not ignore FDA. Ever.

2. Remember point number one.

3. FDA will punish unlawful promotion wherever it finds it – local newspaper ad to national television commercial.

4. Just because FDA doesn't act immediately does not mean you've been given a waiver. In one case, FDA raised concerns for ten years and, in another, the company sold product for five years.

5. As a corollary to point number 4, don't play poker with FDA, thinking it will blink first. While some companies might read these enforcement letters as allowing unlawful conduct to continue for years, we believe this is shortsighted. It is true that FDA might not always act quickly but, when provoked sufficiently, it will move and the impact of non-compliance can be sudden, such as an immediate need for rapid corrective action or product sale stoppages.

6. Companies must answer affirmatively if FDA asks, "Can you hear me?" Remember point number one.

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