



## One Thing Leads to Another: FDA Enforcement in One Area Bleeds into a Second

Alan G. Minsk and Kelley C. Nduom

In the immortal words of the new wave band, The Fixx, one thing leads to another. Ask the latest drug manufacturer that received a Warning Letter from the Food and Drug Administration (FDA) for selling unapproved new drugs.<sup>1</sup> In this case, FDA issued a Warning Letter to the company in July 2013, primarily for violations of current Good Manufacturing Practice requirements. However, in a by-the-way, while-we-have-your-attention fashion, the agency noted that the company was marketing unapproved prescription drugs. Citing its 2011 “Marketed Unapproved Drugs -- Compliance Policy Guide” (CPG), (click [here](#)<sup>2</sup> for AGG’s Bulletin on the CPG) FDA reminded the firm that it must submit a marketing application to obtain approval or discontinue sale.

The Warning Letter is a reminder that FDA remains concerned about the continued sale of unapproved new drugs. However, it is also a reflection of FDA’s typical enforcement approach in this area -- namely, it will not likely proactively seek enforcement action against a company merely for selling such products (typically drugs sold pursuant to the Drug Efficacy Study Implementation program). As the letter demonstrates, typically if FDA chooses to pursue enforcement, the agency will add the unapproved drugs to a list of other regulatory transgressions, such as cGMP non-compliance. This approach is consistent with FDA’s guidance in the 2011 CPG, where the agency stated that it would prioritize enforcement against “unapproved drugs that are also violative of the Act in other ways.” In fact, the CPG provides as an example the same scenario presented in the July Warning letter – cGMP violations leading to additional enforcement action against a company’s unapproved drugs. Therefore, a company that is selling such products should consider the submission of a marketing application or stop sale. If this is not in the company’s immediate commercial plans, at a minimum, the firm should ensure that it, or its third-party manufacturer, is in compliance with FDA’s other requirements. The CPG places companies on notice that FDA will not hesitate to seek enforcement against the unapproved drugs if the company is found to have other regulatory concerns.

The Warning Letter is also a reminder that, once FDA is in a company’s facility for an inspection, anything can happen. The agency inspector has broad authority, within certain statutory parameters, to conduct an inspection. An audit intended to focus on one area, such as cGMP compliance, can turn quickly into a review of other areas, such as adverse event reporting, advertising and promotional materials, or, in the case of the July Warning Letter, the manufacture of unapproved new drugs. Therefore, a company must prepare for the unexpected and ensure its entire house is in complete regulatory compliance order.

In FDA’s world, one thing leads to another.

<sup>1</sup> While the enforcement letter is a matter of public record, consistent with AGG’s long-standing policy, we will not identify here the company or specific products.

<sup>2</sup> <http://www.agg.com/FDA-Guidance-Provides-Notice-that-Newly-Marketed-Unapproved-Products-May-be-Subject-to-Immediate-Enforcement-Action-09-28-2011/>

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