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CLIENT ALERT

FDA to Consider Overhaul of Over-the-Counter Drug Approval Process

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On February 24, 2014, the U.S. Food and Drug Administration announced that it will conduct a sweeping review of its current system for approving over-the-counter (OTC) drugs, potentially leading to significant changes for OTC drug manufacturers seeking to bring new products to market, as well as manufacturers of products already on the market.

Under FDA's current approval process for OTC drugs, individual manufacturers do not have to apply for approval each time they want to market a new product. Instead, they can follow the FDA's monograph for the active drug ingredients in the product. Each FDA monograph sets forth manufacturing standards for a specific type of drug. As long as the manufacturer's OTC drug product conforms to the monograph, FDA will consider the drug "generally recognized as safe and effective." Currently, to develop a monograph, FDA must go through a three-step review process, which includes publication of an advance notice of proposed rulemaking, followed by a tentative final monograph, followed by a final monograph.

FDA explained on Monday that in the forty years since this process was established, it has become apparent that the process does not allow the agency to respond quickly enough as new scientific information about various drugs emerges. The current process can also result in significant delays in finalizing monographs. The monograph for topical antimicrobial drugs, for example, has been in tentative form for over twenty years.

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February 2014

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- CPSC Proposes Revisions to Section 6(b) Information Disclosure Rule
- NHTSA Heads Down the Road to New Vehicle-to-Vehicle Communications Regulations
- FDA to Consider Overhaul of Over-the-Counter Drug Approval Process
- New Data Security Legislation On Horizon

The agency hopes to "modernize" the OTC drug approval process to make it "more responsive to emerging safety information and scientific advances." Next month it will hold a public hearing to solicit suggestions from consumers, industry, doctors, pharmacists, and others on how the system could be improved. The public is also invited to submit written comments before or after the hearing. FDA indicated that it is open to any suggestion for modifying the OTC drug approval process, including complete replacement of the entire current statutory and regulatory framework.

Final implementation of a new approval process may still be a long way off at this point, but it could ultimately mean significant changes in the way OTC drugs are approved, and also in FDA's enforcement practices relating to OTC drugs. OTC drug manufacturers should stay apprised of developments as FDA moves forward in this process.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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