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CLIENT ALERT

FDA Enforcement Action Against Manufacturers for REMS Non-Compliance Reflects Agency Priorities During the Pandemic

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Demonstrating ongoing commitment to enforcement of pharmaceutical manufacturers' regulatory obligations to, among other things, establish and maintain identified Risk Evaluation and Mitigation Strategies ("REMS") programs, the U.S. Food and Drug Administration ("FDA") announced it will pull five generic opioids from the market after the products' manufacturers failed to satisfy regulatory requirements associated with the holding of an abbreviated new drug application ("ANDA").

See the FDA's announcement*, available at* https://public-inspection.federalregister.gov/2021-07335.pdf.

FDA's REMS program, codified at section 505-1 of the Food, Drug & Cosmetics Act ("FD&C Act"), is a drug safety protocol required for certain medications that pose serious safety concerns, and just one of the many regulatory requirements and statutory obligations related to the manufacture and marketing of prescription drugs. The program aims to ensure the benefits of the listed drugs outweigh the risks. Unlike other drug safety programs, the program's focus is on preventing, monitoring, and managing a specific serious risk by informing, educating, and reinforcing actions to reduce the frequency or severity of the event. In short, REMS helps FDA address serious safety concerns and mitigates risks to patients by shielding them from poor quality, unsafe, and ineffective drugs.

More specifically, and as set forth in FDA's April 2019 *REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary Guidance for Industry* (available at: https://www.fda.gov/media/100307/download), if FDA determines that a REMS is necessary, the Agency may require one or more REMS elements, which could include a Medication Guide, a patient package insert, and/or a communication plan. FDA may also require elements to assure safe use ("ETASU") as part of a REMS. ETASU may be required if the drug has been shown to be effective, but is associated with a specific serious risk and can be approved only if, or would be withdrawn unless, such elements are required as part of a strategy to mitigate the specific serious risk(s) listed in the labeling of the drug. ETASU may be required for approved drug products that were initially approved without ETASU when other elements are not sufficient to mitigate a serious risk. Specifically, ETASU may include one or any combination of the following requirements:

- Health care providers who prescribe the drug have particular training or experience, or are specially certified;
- Pharmacies, practitioners, or health care settings that dispense the drug are specially certified;

- The drug be dispensed to patients only in certain health care settings, such as hospitals;
- The drug be dispensed to patients with evidence or other documentation of safe use conditions, such as laboratory test results;
- Each patient using the drug be subject to monitoring; or
- Each patient using the drug be enrolled in a registry.

During manufacturer inspections, FDA will assess whether (i) a REMS was adequately implemented, (ii) that related submissions contain accurate and complete information, and (iii) compliance obligations set forth in the drug approval are being met.

FDA wrote that the sanctioned manufacturers had repeatedly failed to file necessary annual reports for the ANDAs and failed to maintain approved REMS, as required by the FD&C Act. FDA's withdrawal of approval for the ANDAs means that the firms may no longer market or sell the drugs. In addition to the business loss, noncompliance with the FD&C Act in general may lead to fines or—for the most serious offenses—criminal enforcement.

FDA's action in this instance may not be challenged, as the ANDA holders waived both their opportunity to speak directly with the regulators and "any contentions concerning the legal status of the drug products," by failing to respond to a September 25, 2020 published notice offering an opportunity for a hearing.

Because of the potential serious adverse enforcement consequences, manufacturers should maintain awareness of FDA's ongoing commitment to monitoring and enforcing compliance with REMS whether the relevant products fall into the innovator or non-innovator category. Manufacturers should further be mindful of the United States Department of Justice Office of Consumer Protection's authority to enforce all elements of the FD&C Act.

TIP: Diligence and active compliance monitoring are paramount to timely filing of reports required under the FD&C Act and for meeting product approval obligations. Moreover, should FDA request a meeting with your firm, you should engage counsel immediately to understand your options and ensure you do not waive your opportunity to be heard.

We note that government orders on the local, state, and federal levels are changing every day, and the information contained herein is accurate only as of the date set forth above.

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For further information or questions on REMS and the regulation of prescription drugs, please contact T. Reed Stephens, Christopher Parker, or your Winston relationship attorney.

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