

Mallinckrodt strongly believes its methylphenidate ER products are safe and effective when used in accordance with the approved labels. We also believe that the U.S. FDA's actions are not supported by sound scientific evidence and are not consistent with the best interests of patients.

Mallinckrodt methylphenidate ER products have consistently met all FDA quality specifications and regulatory requirements. After conducting a search of the FDA's safety database and evaluating the FDA's scientific support, we remain confident in the safety and efficacy of our methylphenidate ER products. Mallinckrodt continues to evaluate available options and hopes to engage in meaningful dialogue with the FDA regarding this matter.