REMS Industry Consortium℠
Innovating Patient Safety. Mitigating Risk.

February 18, 2022

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Room 1102
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RE: REMS Industry Consortium

Dear Dr. Manzo:

On behalf of our members, the REMS Industry Consortium ("RIC") is excited to formally introduce ourselves to the U.S Food and Drug Administration ("FDA"). Incorporated in September 2021, RIC is a non-profit organization representing the perspectives of organizations that manufacture and sell, or anticipate manufacturing and selling, prescription drugs or biologics subject to Risk Evaluation and Mitigation Strategies ("REMS"). We are currently led by a board of directors comprised of six founding companies: Amneal Pharmaceuticals, Bristol-Myers Squibb, The Janssen Pharmaceutical Companies of Johnson & Johnson, Jazz Pharmaceuticals, Teva Pharmaceuticals, and Viatris.

RIC appreciates FDA's participation in our initial planning meeting in November 2020. FDA's input was vital to the formation of RIC. We aim to improve patient safety and access to medications through REMS innovations. To accomplish this vision, RIC empowers collaboration between all REMS stakeholders. For example, RIC aspires to establish best practices for manufacturers, sponsors, and support vendors; identify streamlined processes; and develop educational resources. In sum, RIC seeks to promote the advancement of science for drug safety and risk mitigation.

FDA engagement is vital to accomplishing RIC's goals. RIC is eager to assist with FDA's REMS-related goals, such as the establishment of best practices in developing shared REMS systems and the modernization and improvement of REMS assessments. Through regular communication, RIC can support REMS-related initiatives and work towards the common goal to protect public health and ensure patient safety. For example, RIC recognizes FDA's leadership with CodeX's REMS Use Case, which targets modern data standards and infrastructure to enable integration across workflows. We sincerely appreciated FDA's notice of the public discovery session and look forward to further engagement.

RIC requests biannual meetings with FDA to share our annual roadmap and strategic plan. We intend to openly discuss how RIC can best support new and ongoing Agency goals. RIC is eager to provide collaborative solutions for recurring challenges across the REMS industry. Importantly,

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RIC is ready to provide balanced, experienced feedback to help strengthen the foundation of FDA REMS initiatives. We look forward to many innovative discussions that aim to identify best practices across the risk management spectrum.

Sincerely,

REMS Industry Consortium Board of Directors

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