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LIFE SCIENCES
ALERT

FDA SEEKS PUBLIC COMMENT ON QUESTIONS RELATED TO DRUG AND BIOLOGICAL PRODUCT SHORTAGES

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Pursuant to the Food and Drug Administration Safety and Innovation Act (FDASIA) signed into law on July 9, 2012, the Food and Drug Administration (FDA) has been implementing procedures to more effectively tackle the drug shortage issues. This comes after the presidential Executive Order 13588 signed by President Obama on Oct 11, 2011, giving the FDA the necessary powers to address the shortage issue.

In a recent Federal Register Notice posted yesterday, the FDA announced that it is seeking public comments from interested persons on certain questions related to the drug and biological product shortages. Accordingly, the FDA's Drug Shortages Task Force is seeking comments from the public on issues related to the development of a drug shortage plan for prevention and mitigation of both drug and biological product shortage.

A sample of questions presented in the Notice include:

- What metrics do manufacturers currently use to monitor production quality?
- To what extent do purchasers and prescribers use information about manufacturing quality when deciding how to purchase or utilize products?
- What kinds of manufacturing quality metrics might be valuable for purchasers and prescribers when determining which manufacturers to purchase from or which manufacturers' products to prescribe?
- What kinds of manufacturing quality metrics might be valuable for manufacturers when choosing a contract manufacturer? How frequently would such metrics need to be updated to be meaningful?
- Is it possible to design a qualified manufacturing partner program that would have a positive impact on drug shortages?
- Are there incentives that FDA can provide to encourage manufacturers to establish and maintain high-quality manufacturing practices, to develop redundancy in manufacturing operations, to expand capacity, and/or to create other conditions to prevent or mitigate shortages?
- Are there incentives from other US Government Agencies that can provide, separately or in partnership with FDA, to prevent shortages?
- Are there changes to these existing tools that FDA can make to improve their utility in managing shortages?
- Are there other actions that FDA can take under its existing authority to address impending shortages?
- Are there other communication tools that FDA should use or additional information the Agency should share to help health care professionals, manufacturers, distributors, patients, and others manage shortages more effectively?
- Are there changes to our public shortage Web sites that would help enhance their utility for patients,

prescribers, and others in managing shortages?

- What impact do drug and biological product shortages have on research and clinical trials?
- What actions can FDA take to mitigate any negative impact of shortages on research and clinical trials?
- What other actions or activities should FDA consider including in the strategic plan to help prevent or mitigate shortages?

Comments can be made electronically or by mail until March 14, 2013. All submissions must include the agency name and Docket No. FDA-2013-N-0124. If you wish to present a comment in response to the FDA Notice or have questions about this alert, please contact Shahnam Sharareh at 609.844.3030 or sshararehh@foxrothschild.com or David Restaino at 609.895.6701 or drestaino@foxrothschild.com.

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