BD Statement on FDA Warning Letter for Preanalytical Systems Business Unit

PR Newswire

FRANKLIN LAKES, N.J., Jan. 12, 2018 /<u>PRNewswire</u>/ -- BD (Becton, Dickinson and Company) (NYSE: BDX) issued the following statement in response to receiving a warning letter from the U.S. Food and Drug Administration for its Preanalytical Systems business unit.

Richard Byrd, worldwide president of BD Preanalytical Systems said: "Ensuring the safety and quality of our products is our top priority at BD, and we are dedicated to maintaining a robust quality system to fulfill this commitment. We take any potential issue with our products very seriously and are cooperating fully with FDA on this matter. After the FDA inspection in July, we took prompt action that we believed fully addressed the agency's inspectional observations. We are carefully reviewing the agency's feedback outlined in yesterday's letter with the highest sense of urgency, and we will provide a full response to FDA on or before their Feb. 1 deadline. We will continue to demonstrate our commitment to serving the public health as well as meeting FDA's expectations."

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help improve patient outcomes, improve the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to better diagnose disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. In 2017, BD welcomed C. R. Bard and its products into the BD family. For more information on BD, please visit bd.com.

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