



July 20, 2015

DuPont™ Tyvek® Medical Packaging Transition Project (MPTP)

Open letter to the medical packaging industry,

For more than 40 years, DuPont™ Tyvek® has helped protect the health of millions of patients worldwide by helping pharmaceutical and medical devices to remain clean and sterile. We have accomplished this by understanding the needs and requirements of the medical device industry and being committed to working closely with sterile packaging manufacturers (SPMs) and medical device manufacturers (MDMs) to deliver proven solutions to meet those needs – past, present and well into the future. The MPTP is proof of our long-term commitment to the industry and to our customers around the world. Recently, we have noticed communications that are causing concern and confusion so I am writing this letter to reassure you of DuPont's ongoing commitment and support.

Our understanding of the medical device industry and regulatory requirements related to sterile barrier systems around the world were the basis for the Tyvek® Transition work. This meticulous process was not entered into lightly and has taken the better part of four years to bring to fruition. Since the beginning of this project, DuPont has worked closely with SPMs and MDMs to support various efforts related to the Tyvek® Transition, including: cell builds; making Tyvek® Transition material available for testing; providing detailed ongoing information through our website, numerous global webinars, and in-person meetings; and by working with customers to address specific requests. All of this DuPont embraced on behalf of the medical device industry, an effort unlike any other, to reduce the burden on the MDM and place the majority of the testing burden on us, the material supplier.

After four years of preparation and communication, we are still on track to begin commercialization once we receive U.S. FDA affirmation of functional equivalence, which is expected in September of this year. At the same time, we recognize that some MDMs, especially those with Class III devices sold in Europe, have expressed concern that they may need a little more time for Notified Body approvals. As a result, we have decided to increase the mix of Current and Transition material available to our customers for the remainder of 2015 to support industry needs.

In fact, 2015 will be a record production year for Tyvek® sold into medical and pharmaceutical packaging. While we expect to ship more medical packaging product this year than any other year in recent history, the demand for these products is more than 40% higher than this same time last year. As a result, we have had to implement a managed distribution plan. Additionally, one of the key benefits of the Tyvek® Transition is the increased manufacturing capabilities, which will allow Tyvek®1073B and Tyvek® 1059B to be produced in multiple locations around the world. We expect that once a large portion of our customers transition, managed distribution will no longer be necessary. It is

critical that you continue to complete your change control processes, risk assessments and regulatory submissions so that you are prepared to accept Tyvek® Transition material interchangeably as soon as possible. Although we have not announced a specific date for discontinuing Current material, I can assure you our decision will be aligned with the needs of our customers and sufficient notice will be given to plan accordingly with minimal disruption to MDMs.

We look forward to continuing to support MDMs, as we have throughout the Medical Packaging Transition Project and for the past 40+ years. We will continue to provide multiple ways for you to stay informed, including our website, [www.transition.tyvek.com](http://www.transition.tyvek.com); our global webcasts; face-to-face seminars; or you can request an individual meeting with a member of our global team.

I appreciate your business and look forward to working together to meet the needs of the medical packaging industry for years to come.

Sincerely,



Margaret Pyers

Global Marketing Manager

DuPont Medical Packaging