Michael H. Scholla, PhD



DuPont™ Tyvek® Medical Packaging Transition Project (MPTP)

Dear Customers,

After years of preparation, collaboration and execution of the Medical Packaging Transition Project (MPTP), we are delighted to report that, as expected, package data for Pre-sterilization, Post-sterilization, 1-, 3- and 5-year accelerated aging, and 1-year real-time aging is complete and indicates Functional Equivalence between Current Tyvek® and Tyvek® Transition material produced on our newer manufacturing assets. This is a huge accomplishment for all involved and will help to ensure the continuity and flexibility of future Tyvek® supply into medical and pharmaceutical packaging applications worldwide.

We are currently in the process of preparing the 3- and 5-year accelerated aging and 1-year real-time aging reports for submission to the U.S. FDA, Health Canada and the five Notified Bodies in June and July. Once these submissions are complete, we will notify you so that you may reference our reports in your submissions to: BSI Assurance UK, Ltd.; LNE/G-MED; SGS United Kingdom Limited; TÜV Rheinland LGA Products GmbH; and TÜV SÜD Product Service GmbH.

We are extremely proud of the results accomplished to date and the engagement we have seen from customers around the world. We expect U.S. FDA affirmation of Functional Equivalence in September and are on track to begin commercial sales in October. Therefore, it is essential that you work with your SPM suppliers and continue to move forward and complete your change control processes, risk assessments and regulatory submissions to the Notified Bodies so that you are able to accept the Tyvek® Transition Material this fall.

As always, we will continue to provide multiple ways for you to stay informed including updates to our website, www.transition.tyvek.com; face-to-face seminars; live chat Q&A sessions through the on-line Medical Packaging Community; or you can always request an individual meeting with a member of our global team.

Thank you for your business and ongoing engagement.

August Pyers

Beny Allen York

Bruce A. Yost, PhD

Global Marketing Manager Global Technical Director Global Regulatory Director