



145 James Way, Southampton, PA 18966  
215-526-2300 • Fax: 215-526-2191  
info@newageindustries.com • www.newageindustries.com

August 4, 2022

**Re: Update to DCR 2331 – Phase II Additional Extrusion Lines**

Original Notification Date: July 21, 2020

1<sup>st</sup> Update: September 2, 2020

2<sup>nd</sup> Update: March 9, 2021

3<sup>rd</sup> Update: August 5, 2021

4<sup>th</sup> Update: November 30, 2021

5<sup>th</sup> Update: February 8, 2022

**Subject:**

NewAge Industries AdvantaPure® Tubing and Hose Manufacturing Location Expansion – **PHASE II**

**Change Description:**

This letter serves to notify our customers about the qualification of an additional extrusion line for AdvantaFlex® TPE Biopharmaceutical Tubing. NewAge® Industries has completed the IQ/OQ/PQ for this additional extrusion line and has approved it for production.

**Affected Product Part Numbers**

AdvantaFlex TPE tubing				
Material	Description	Catalog Part Number	Product Family Number	Raw Material Number
TPE	AdvantaFlex Biopharmaceutical Grade TPE Tubing	APAF-BP-xxxx-xxxx	A750	P50102-64

**Change Impact Assessment:**

NewAge Industries has completed the qualification which includes the installation and validation of one (1) additional extrusion line for AdvantaFlex TPE Tubing. The additional line is located in a certified ISO 7 cleanroom. The ISO 7 suite was built and designed to adequately handle the demands of two (2) production lines in the same suite. The room was confirmed and re-qualified in both an at-rest and operational state to ensure the highest quality standards will continue to be met. The validation summary for the new AdvantaFlex extrusion line is available for customers upon request.

**Implementation Date:**

As of July 11, 2022, the AdvantaFlex® TPE Tubing part numbers outlined above have been released for distribution. Customers can review the validation data for the part numbers affected by this change. A new site validation summary is available upon request as well as the associated equipment and product specific validation activities. With the data collected, product performance has been verified to be comparable and meets all product specifications.

**Next Steps:**

It is anticipated that in the next 6-8 weeks we will be releasing an additional Platinum Silicone Extrusion line.

Please take this opportunity to contact our Customer Service Representative Team at (215) 526-2151 or email [compliance@newageindustries.com](mailto:compliance@newageindustries.com) should you have any questions or concerns.

Other change notifications and details about our Change Notification Policy can be found on our website at <http://www.advantapure.com/change-notifications.htm>. Thank you for your continued support of NewAge Industries AdvantaPure®.

Sincerely,



Paula Martinelli  
Life Sciences Product Manager



Mary Marcus  
Executive Director of Quality