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February 8, 2022

Re: Update to DCR-2331 – Final Change Notification

Original Notification Date: July 21, 2020

1st Update: September 2, 2020

2nd Update: March 9, 2021

3rd Update: August 5, 2021

4th Update: November 30, 2021

Subject:

NewAge Industries AdvantaPure® Tubing and Hose Manufacturing Location Expansion

Change Description:

This letter serves as the **Final Change Notification**, shared previously in the above-mentioned communications. As initially communicated, NewAge Industries has completed the Phase 1 validation of a new manufacturing location (using the same make and model equipment) at 364 Valley Rd., Warrington PA 18976 to manufacture AdvantaSil® and AdvantaFlex® tubing.

The new facility and manufacturing processes have completed a full qualification and validation with IQ/OQ/PQ, tubing tolerances and biological testing. Product performance has been verified to be comparable and meets all product specifications.

Affected Product Part Numbers:

AdvantaSil® Silicone tubing <i>*All catalog sizes are affected by this change</i>		AdvantaFlex® TPE tubing <i>*All catalog sizes are affected by this change</i>	
Catalog Part Number	Description	Catalog Part Number	Description
APST-xxxx-xxxx	Unreinforced Silicone Tubing	APAF-BP-xxxx-xxxx	AdvantaFlex Biopharmaceutical Grade TPE Tubing
APSPG-xxxx-xxxx	Silicone Pump Grade Tubing		
APHP-xxxx-xxxx	Braid-Reinforced Silicone Hose		
APSH-DB-xxx	Double-Braided Silicone Hose		
APSW-SP-xxxx	4-Ply, Wire-Reinforced, Mandrel Silicone Hose		
APLT-xxxx-xxxx	Ultra-Low Temperature Silicone Tubing		

Change Impact Assessment:

Phase I

The new 8,400 ft² manufacturing facility with ISO 7 & 8 certified cleanroom space has extrusion capacity, assuring redundancy and security of supply, to better serve NewAge Industries AdvantaPure® customers.

AdvantaSil® and AdvantaFlex® tubing made in Southampton (existing manufacturing site) and Valley Rd. (new manufacturing site) will have the same part number and label, and a new lot number will be provided. Refer to the Change Assessment below for additional information:

Change Assessment	Impact
Traceability of Product	The lot number of products made at the Valley Rd. Warrington site will start with a “VR” indicating the site of manufacture. We are holding product in quarantine for the customers who require approval on the new manufacturing location.
Part Number	Not impacted by this change
Lot Number	The lot number of products made at the Valley Rd. Warrington site will start with a “VR” indicating the site of manufacture.
Product Label	Not impacted by this change
New site Master Validation (IQ/OQ/PQ) & Executive Summary	Available to customer upon request and during customer audit (under current NDA).
Product Validation Guides/ Summaries	The existing guides are available to customers upon request.
Raw Material	Not impacted by this change
Manufacturing Process	Not Impacted by this change
Testing Methods	Remains the same
Quality Control	Remains the same
Assembly/ Manifold Part Number	*Assemblies may integrate tubing manufactured from the new manufacturing location (Valley Rd. site).
Regulatory Claims	Not impacted by this change
Form, Fit or Function	Not impacted by this change
Product Released Criteria	Not impacted by this change

**Contact your NewAge Representative with questions*

Implementation Date:

A Validation Summary for the new site is available to customers upon request. Product performance has been verified to be comparable and meets all product specifications.

Therefore, Phase I of this project is considered complete. All AdvantaFlex® catalog parts outlined above will be available for distribution beginning February 4, 2022 and AdvantaSil® Silicone on March 4, 2022.

The validation data for the products affected by this change is currently available for review. Customers are welcome to schedule an audit of the new Valley Rd. manufacturing site using the current NewAge Industries procedures.

Status/ Date	Valley Rd. Extrusion Expansion (Phase I)
October, 2021	Construction of Phase I of the new manufacturing facility/ equipment installation / Cleanroom Static Qualification
December, 2021	Extrusion lines are in place for Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)
January, 2022	Clean room Operational Qualification / System Performance Qualification
February, 2022	Three (3) extrusion suites are fully approved / validation completed and executive summary report (including the results of each qualification stage and subsequent product testing) is available
February, 2022	Customer samples are available / Product Impact Testing
February 4, 2022	AdvantaFlex® TPE tubing release Customer's Acceptance of Change is required back within 30 days
March 4, 2022	AdvantaSil® Silicone tubing release Phase I fully approved

Next Steps:

If you have previously indicated formal acceptance is required for this change, you will be required to sign the attached Acceptance of Change form, and return it within **30 days**. Please take this opportunity to contact your Customer Service Representative at (215) 526-2151 or email compliance@newageindustries.com should you have any questions or concerns. Thank you for your continued support of NewAge Industries AdvantaPure®.



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Life Sciences Product Manager



Mary Marcus
Executive Director of Quality