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Change Notification Letter

Date Issued: July 21, 2020

Change Notification Number: DCR 2331

Subject: AdvantaPure® AdvantaFlex® Biopharmaceutical Grade TPE Tubing Extrusion Expansion

Effective Date: A new facility is expected to be completed Q4, 2020. The redundant manufacturing cleanroom space is expected to be operational Q1, 2021.

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Dear Valued Customer,

This letter serves as formal notification of changes that may affect products or services purchased by your organization.

Scope of Notification:

Part Series Affected:

A750, A760, A761, A762, A765, A767, CA750, CA761, CA762, CA763, CA764, CA765, CA767, CA768, CSA761, CSA762, CSA765, CA892

Description of Change:

NewAge® Industries AdvantaPure is expanding its extrusion capacity for making AdvantaFlex Biopharmaceutical-grade TPE tubing.

Important Points of Note:

- The additional ISO 9001:2015 space will be located in a company-owned building in Warrington, PA, seven miles from company headquarters.
- Like for like equipment to what is presently being used will be purchased for this new space.
- There will be no raw material or manufacturing process changes made.
- There will be no interruption to our current manufacturing process for AdvantaFlex tubing, thus ensuring our supply of product to current and new customer requests. Once commissioned, the new extrusion space will provide additional capacity to the current operation to meet future market demand.
- Upon certification, the AdvantaFlex product made in the new space will undergo third-party extractables testing to the BPOG/RX360 standard.
- A milestone and timeline schedule will be shared during the expansion project.
- Environmental testing of the space will be performed and documented.
- All new manufacturing equipment qualified in the new ISO 14644 certified cleanroom space will go through NewAge Industries IQ (Installation Qualification), OQ (Operational Qualification) and PQ (Performance Qualification) validation processes.
- An Executive Summary will be made available at the conclusion of the project.
- The new manufacturing space should be available for audits upon completion of the qualification activities. If you will require an audit of the new space, inquire at compliance@newageindustries.com.

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Should you have any questions regarding this notice, please contact us at compliance@newageindustries.com. 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.



Gregg Donovan

AdvantaPure Product Manager

