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Change Notification Letter

Date Issued: July 10, 2020

Change Notification Number: DCR 2313

Subject: AdvantaPure® AdvantaFlex® Biopharmaceutical Grade TPE Mold Shop Expansion

Effective Date: 4th Quarter 2020

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 - A751 - A760 - A761 - A762 - A765 - A767 - CA750 - CA751 - CA752 - CA754 - CA760 - CA761 - CA762 - CA763 - CA764 - CA765 - CA766 - CA767 - CA768 - CSA761 - CSA762 - CSA765

Description of Change:

NewAge® Industries AdvantaPure Products is expanding the existing Mold Shop area by almost 40%. The reason for the expansion of the AdvantaFlex Mold Shop is to increase capacity, efficiencies, and ease of material flow.

Important Points of Note:

- This expansion project does not install or remove permanent walls.
- The existing process parameters will not change.
- The same Quality Inspection release process and criteria will be maintained in the expanded space.
- Environmental testing of the newly renovated molding area will be performed. Testing will consist of an assessment of both viable & non-viable impact on the environment.
- Validated sterile AdvantaFlex assemblies (CSA761, CSA762, and CSA765) will undergo an impact assessment.
- An Executive Summary will be made available at the conclusion of the project.
- The AdvantaFlex Mold Shop will be required to shut down on or about October 1st for testing.
 Operations are expected to resume on or about October 14th.

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

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AdvantaPure Product Manager





