



**ESOP** Employee Owned  
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## Change Notification Letter

**Re:** Update to DCR 2631  
**Original Notification Date:** June 4, 2021 - **Update:** July 19, 2021  
**Subject:** Cleanroom Expansion Update at NewAge® Industries AdvantaPure®

Dear Valued NewAge Industries AdvantaPure Customer:

This letter serves as an update to our earlier communication of the cleanroom expansion taking place at NewAge Industries AdvantaPure's headquarters located in Southampton, PA. Below you will find the updated details into the planned qualification activities to take place as a result of this expansion.

### **Timeline: Update**

The cleanroom construction and as-built qualification turnover will be completed by the end of July of 2021. Upon turnover from the construction firm, qualification activities are planned to take place immediately following.

### **Overview:**

This expansion project will add to the existing 20,000 sq. ft. cleanroom space located at 145 James Way, Southampton, PA. The new space will be utilized to increase Single-Use assembly and molding capacity. All policies and procedures related to our current Single-Use systems will remain the same. The expansion and subsequent start-up is expected to have little impact on current production.

### **Qualification Testing: Update**

As part of the expansion qualification activities, the new 3,100 sq. ft. addition will be certified to ISO 7 standards. The room qualifications and certifications will occur under as-built, at rest, and operational conditions consisting of non-viable and viable particulate sampling. The viable testing will assure the product and the cleanroom are producing quality parts similarly to our existing cleanrooms. Upon completion of the initial qualification testing, the room will be integrated into our routine environmental monitoring program, undergoing increased monitoring levels thereafter. New injection molding presses, and any relocated as a result of the expansion, will undergo qualification activities following an IQ/OQ/PQ validation approach. In addition, representative product samples will be subjected to bioburden testing to ensure no environmental impact on the product quality has occurred. It is anticipated that molded assemblies built after August 9, 2021 will be produced out of our newly expanded area.

### **Communication: Update**

This notification update is a follow-up to the original communication with updates to timelines and qualification activities.



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Cleanroom Expansion  
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Should you have any questions regarding this notice, please contact your Customer Service Representative at 215-526-2151. 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,



Mary Marcus  
Director of Quality  
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