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Change Notification Letter

Date Issued: June 4, 2021
Change Notification Number: 2631
Subject: Cleanroom Expansion
Effective Date: July 28, 2021

Dear Valued Customer,

This letter serves as communication of our cleanroom expansion project taking place at NewAge® Industries' headquarters located in Southampton, PA. Below you will find the greater details into the planned qualification activities scheduled to take place as a result of this expansion.

Timeline:

Planning and design activities began in the first quarter of 2021 and construction began in April of this year. It is expected that the cleanroom construction and as-built qualification turnover will be completed by the end of July of 2021. Upon turn over 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:

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. 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 4, 2021 will be produced out of our newly expanded area.

Communication:

A follow-up to this communication with updates on timelines and qualification activities will be sent approximately one (1) month prior to the effective date.

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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,

A handwritten signature in blue ink, appearing to read "Mary Marcus".

Mary Marcus
Director of Quality

E-mail: Compliance@newageindustries.com