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October 28, 2019

Change Notification: DCR – 2189

Effective date: January 26, 2020

NewAge Industries/AdvantaPure Gamma-Irradiation Dose Range Notification

Dear Valued Customer:

Background:

NewAge Industries/AdvantaPure positions itself to continually anticipate and exceed the evolving needs of the pharmaceutical and biopharma industries. AdvantaPure is ISO 9001:2015 certified. All products are manufactured, stored, and shipped under the highest controls possible to ensure unsurpassed product purity for the customer. Because of these standards, this notification is to inform you of planned changes to our maximum gamma-irradiation dosing limit applied to custom assemblies requiring gamma-irradiation.

Description of Change(s):

Our current maximum processing dose is either 40kGy or 45kGy. We are consolidating the maximum processing dose to 40kGy. This gamma processing dose consolidation will apply to both gamma-irradiated and sterile gamma-irradiated systems.

Reason for Change:

NewAge will be moving to one standard maximum dose in order to streamline gamma processing. This process improvement will support customer demands while reducing the opportunity for error.

Scope of Impacted Products:

This change notification applies to all products manufactured requiring gamma-irradiation or gamma sterilization processing.

Change Impact Assessment:

While our internal processes will change to support this initiative there will be minimal to no affect to our customers. All certificates of gamma processing and any documentation will state a maximum dose of 40kGy. On any documentation where the current dose specification is written as 25kGy-

45kGy, it will remain unchanged because the consolidated dose range is within specification. There will be no impact to the sterilization validations.

The adoption of the 25kGy-40kGy gamma dose range will have no effect on and will not change the product's form, fit, or function, product claims, manufacturing process, testing methods, or product quality release requirements.

Implementation Date:

The adoption of the standard 25kGy-40kGy gamma dose range will be effective January 26, 2020.

If you have any questions or concerns regarding these changes, please feel free to contact me at mmarcus@newageindustries.com or 215-523-2300.

Respectfully yours,

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

Mary Marcus
Director of Quality, ASQ – CMQ/OE, CCGB, CQE