

Valentin-Rodriguez, Celimar

From: Joe Rodgers <RodgersJ@Theragenics.com>
Sent: Monday, March 30, 2015 11:17 AM
To: Valentin-Rodriguez, Celimar
Cc: Herrera, Tomas; Sepulveda, Lymari
Subject: RE: Theragenics Response to NRC RAI 021915 - IsoCartridge

Categories: SSD

Celimar,

My responses follow your questions below.

Let me know if you have any questions.

Best regards,
Joe

Joseph J. Rodgers, M.S.
Director of Radiation Physics, Technical Support, & Customer Service
Theragenics Corporation
5203 Bristol Industrial Way
Buford GA 30518
770-831-4181 (o)
770-831-4369 (f)
www.theragenics.com

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From: Valentin-Rodriguez, Celimar [<mailto:Celimar.Valentin-Rodriguez@nrc.gov>]
Sent: Monday, March 30, 2015 10:01 AM
To: Joe Rodgers
Cc: Herrera, Tomas; Sepulveda, Lymari
Subject: RE: Theragenics Response to NRC RAI 021915 - IsoCartridge

Good Morning Mr. Rodgers,

After reviewing Theragenic's response to our 2nd RAI, we need clarification of the following information.

1. Please confirm that the outer tray with attached "vial" label will be on the IsoCartridge whenever the device is loaded onto the IsoLoader workstation. Also, confirm our understanding that **there is no label attached to the IsoCartridge itself**, and that **the only labels will be attached to the plastic tray covering the IsoCartridge**. - **Confirmed**
2. Please confirm that the plastic tray covering the IsoCartridge will have the attached "vial" label whenever the IsoCartridge is loaded with seeds. – **Confirmed**.

3. Please confirm that the IsoCartridge end users will receive *Instructions of Use* for the IsoStrand module, and that the instructions will include a process to ensure that the seeds in the IsoStrand have not been damaged or compromised before use. – **Confirmed.**

Please contact me if you have any additional questions or concerns.

Best Regards,
Celimar

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Celimar Valentin-Rodriguez, Ph.D.
General Engineer
U.S. Nuclear Regulatory Commission
NMSS/MSTR/MSLB
301-415-7124

From: Joe Rodgers [<mailto:RodgersJ@Theragenics.com>]
Sent: Thursday, March 26, 2015 12:57 PM
To: Valentin-Rodriguez, Celimar
Cc: Herrera, Tomas
Subject: Theragenics Response to NRC RAI 021915 - IsoCartridge

Celimar,

Attached is our response to your letter dated February 19, 2015 regarding additional Information for the SSD application, IsoCartridge submitted on October 21, 2014 and responses submitted dated January 19, 2015.

Please let me know if you have any questions.

Best regards,
Joe

Joseph J. Rodgers, M.S.
Director of Radiation Physics, Technical Support, & Customer Service
Theragenics Corporation
5203 Bristol Industrial Way
Buford GA 30518
770-831-4181 (o)
770-831-4369 (f)
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