

Miller, Debra

From: Joe Rodgers <RodgersJ@Theragenics.com>
Sent: Wednesday, January 15, 2014 9:11 AM
To: Jankovich, John
Subject: Theragenics Corporation SSDR Amendments - GA645S101S (TheraSeed Model 200) and GA645S102S (I-Seed Model AgX100)

John

I received your call back in September 2013 and needed to follow up with you.

I submitted two amendments to the Georgia Department of Natural Resource – RMP on May 20, 2013 for GA645S101S and GA645S102S.

Since the NRC is now responsible for the approval of these amendment requests, I was checking to see if you had any updates on these amendments.

A summary of each amendment request is provided below.

GA645S101S (TheraSeed Model 200)

This amendment includes the following changes and updates:

1. Packaging and labeling of TheraSeed® Model 200 loaded in C20® Magazines.
2. Packaging and labeling of TheraSeed® Model 200 loaded in IsoCartridge®
3. Packaging and labeling of TheraSeed® Model 200 loaded in seed carriers for eye plaques.
4. Labeling of TheraLoad®, TheraSleeve®, TheraStrand® and TheraStrand® RT with TheraSeed® Model 200.

GA645S102S (I-Seed Model AgX100)

This amendment includes the following changes and updates:

1. Increase the maximum activity from 10 mCi (apparent) [20 mCi (contained)] to 20 mCi (apparent) [40 mCi (contained)].
2. Packaging and labeling of AgX100® seeds loaded in C20® Magazines.
3. Packaging and labeling of AgX100® seeds loaded in IsoCartridge®
4. Packaging and labeling of AgX100® seeds loaded in seed carriers for eye plaques.
5. Labeling of TheraLoad®, TheraSleeve®, TheraStrand® and TheraStrand® RT with I-Seed Model AgX100®.

I attempted to send the amendment updates via email to Margie Kotzalas on August 26, 2013 but the file size (15MB) was too large to be received.

Do you have a way to receive larger file sizes electronically?

Please contact me if you have any questions.

Best regards,
Joe

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