

Miller, Debra

From: Jankovich, John
Sent: Thursday, January 16, 2014 11:33 AM
To: Joe Rodgers
Cc: Herrera, Tomas
Subject: Files on CD are not legible

Joe,
I received the CD. However, Attachments A-N (with the exception of the photos) are not legible in either of the two pdf files. All what is visible is just a blur in place of the text.

Could you send a replacement.
Thank you.
John

From: Joe Rodgers [mailto:Rodgers@Theragenics.com]
Sent: Wednesday, January 15, 2014 4:06 PM
To: Jankovich, John
Cc: Kotzalas, Margie; Herrera, Tomas
Subject: RE: Theragenics Corporation SDR Amendments - GA645S101S (TheraSeed Model 200) and GA645S102S (I-Seed Model AgX100)

John

Thanks for the prompt reply. I am sending a CD with the two amendment request to you via FedEx for delivery tomorrow.

I respectfully request the amendment request for the GA645S102S (SSD-14-61) to be reviewed first as a priority.

Please let me know if you have any questions.

Best regards,
Joe

Joseph J. Rodgers, M.S.
Director of Radiation Physics, Technical Support, and Customer Service
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From: Jankovich, John [mailto:John.Jankovich@nrc.gov]
Sent: Wednesday, January 15, 2014 3:17 PM
To: Joe Rodgers
Cc: Kotzalas, Margie; Herrera, Tomas
Subject: RE: Theragenics Corporation SDR Amendments - GA645S101S (TheraSeed Model 200) and GA645S102S (I-Seed Model AgX100)

Joe,
In response to your question, please note that we received the files from Georgia in hard copy format. We assigned case #s SSD-14-60 and SSD-14-61 to your registration certificates to be transferred to the NRC. We received Theragenics' files in November 2013, and I presume that your amendment request, dated May 20, 2013, is among the other documents which we received from Georgia. The NRC maintains all records in electronic form, but we have not scanned your files yet, thus, I have no ready access to determine whether the amendment request is indeed among the documents.

However, if you could send us the amendment request, dated May 20, 2013, in electronic form, we could save the scanning step in the process and the quality of the records will be better. Therefore, I ask you that please send me it in electronic form. I think that CDs would be the best format. I will make sure that the e-copy documents will be placed in the NRC's electronic records.

Please send the CDs to my attention:

John P. Jankovich
Mail Stop T-8E24
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

If you have further questions, please contact me again by e-mail or on the phone at 301 415-7904.
John

John P. Jankovich, Ph.D.
Team Leader
Sealed Source and Device Registrations
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555

From: Joe Rodgers [<mailto:RodgersJ@Theragenics.com>]
Sent: Wednesday, January 15, 2014 9:11 AM
To: Jankovich, John
Subject: Theragenics Corporation SSTR 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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