



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, D.C. 20555-0001

October 31, 2017

Theragenics Corporation
ATTN: Joseph J. Rodgers
5203 Bristol Industrial Way
Buford, GA 30518

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR THERAGENICS
CORPORATION SEALED SOURCE AND DEVICE REGISTRATION
NOS. NR-0645-S-101-S AND NR-0645-S-102-S

Dear Mr. Rodgers:

This letter is in response to your letter dated September 13, 2017, requesting to amend your Sealed Source and Device Registrations Nos. NR-0645-D-101-S and NR-0645-D-102-S. In reviewing your information, we find that additional information is required to complete our review. In the enclosure to this letter, we have summarized the issues not addressed in your application.

Please be aware that you may request that certain portions of your submittal to the NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate.

Please submit the requested information within 30 calendar days of the date of this letter. If we have not received complete information within 30 days, we will consider your request as having been abandoned by you. This is without prejudice to the submission of a complete new request.

If you have any questions, please contact me at Lymari.Sepulveda@nrc.gov or at (301) 415-5619.

Sincerely,

/RA/

Lymari Sepulveda, Mechanical Engineer
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Request for Additional Information

REQUEST FOR ADDITIONAL INFORMATION FOR THERAGENICS CORPORATION
SEALED SOURCE AND DEVICE REGISTRATION NOS. NR-0645-S-101-S AND
NR-0645-S-102-S

Date: October 31, 2017

Certified Mailing No. 7015 3010 0000 7901 7359

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OFC	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB
NAME	LSepulveda	THerrera	LSepulveda
DATE	10/31/17	10/31/17	10/31/17

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Theragenics Corporation Amendment Request Dated September 13, 2017, Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Theragenics Corporation amendment request dated September 13, 2017, and determined that additional information is needed in order to continue with our review. Please address the issues listed below. This information is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.210, and described in the relevant guidance document NUREG-1556, Volume 3, titled "Applications for Sealed Source and Device Evaluation and Registration."

1. Please specify the lot number of the last unit that was distributed by Eckert & Ziegler BEBIG, Inc. (Eckert & Ziegler) before the Theragenics Corporation (Theragenics) assumed ownership of the Eckert & Ziegler business line and the number of completed units, if any, that were transferred to Theragenics.

2. NUREG-1556, Volume 3, Revision 2 contains information regarding ownership changes. In most cases the registration certificate is transferred to the new owner; however Theragenics is requesting that the VariStrand, Standard Strand, RTS (VariStrand RT), AnchorSeed, and AnchorLoad be added to NR-0645-S-101-S and NR-0645-S-102-S.

Please either provide a description that includes the manufacturing process of the products that Theragenics has taken over from Eckert & Ziegler or identify which references from NR-1289-S-101-S should be added to the Theragenics registration certificates and submit copies to the NRC.

3. Please confirm that the new products VariStrand, Standard Starnd, RTS (VariStrand RT), AnchorSeed, and AnchorLoad have been incorpoated into the Theragenics Corporation quality assurance program. Also, please discuss whether any changes were made to the quality assurance program with the inclusion of the new products.

Enclosure