

Georgia Department of Natural Resources

4244 International Parkway, Suite 114, Atlanta, Georgia 30354

Lonice C. Barrett, Commissioner
Environmental Protection Division

Harold F. Reheis, Director
(404) 362-2675

April 23, 1997

Mr. T. Tydings Robin, Jr., Ph.D.
Radiation Safety Officer
Theragenics Corporation
5325 Oakbrook Parkway
Norcross, Georgia 30093

Dear Mr. Robin:

We have received and completed the initial review of your request for amendment to Sealed Source Registration GA 645-S-101-S, palladium TheraSeed® brachytherapy implants. Additional information is required before we can continue the review. The text that follows itemizes any questions we have had to date.

- 1) Please provide details of the Quality Assurance program that relate to the welding precision of the automatic controller for the laser weld (cold assembly).
- 2) Regarding the 100% visual inspection of welds: Are the inspections performed after the completion of each weld (inspect each weld separately), or after the completion of each seed capsule (inspect both welds at the same time)?
- 3) Please state how Theragenics will handle non-conforming items found during the manufacturing process. For instance, state whether they will be reworked, scrapped, et cetera.
- 4) Automated processes often result in changes to existing handling procedures. Please describe any new or revised handling procedures that will be implemented by automating the cold welding process.

Upon receipt of the above information, we will be able to resume your amendment request to GA 645-S-101-S, Model 200 TheraSeed®. If you have any questions, please feel free to give our office a call at (404) 362-2675.

Sincerely,



Eric T. Jameson
Radiological Health Specialist