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

November 5, 1997

Mr. Glenn Dill, Director of Operations
Theragenics Corporation
5325 Oakbrook Parkway
Norcross, Georgia 30093

Dear Mr. Dill:

This letter refers to the inspection conducted by me on October 29, 1997. At the conclusion of SS&D registration certificate GA 645-S-101-S, a discussion of the findings was held with Ty Robin, Ph.D., RSO; Joe Rogers, Sr. Health Physicist; Mark Hughes, Manufacturing Manager; Len Owens, Quality Services Manager; and Janet E. Zeman, Directory of Regulatory Affairs.

The inspection was an examination of the QA/QC procedures and checks identified in the SS&D registration certificate to verify that the TheraSeed® is being manufactured in accordance with the Georgia Department of Natural Resources "Rules and Regulations for Radioactive Materials," Chapter 391-3-17, and as approved by the Department. The inspection consisted of selective examinations of procedures, interviews with personnel, and independent observations by me.

No items of noncompliance with the Department's requirements were found during the inspection.

The Departmental is still reviewing your facsimile dated October 28, 1997 regarding seed activity issues. A response will be forthcoming under a separate cover.

If you have any questions, please feel free to contact our office at (404) 362-2675.

Sincerely,

Eric T. Jameson
Senior Radiological Health Specialist
Radioactive Materials Program

GEORGIA DEPARTMENT OF NATURAL RESOURCES
RADIOACTIVE MATERIALS PROGRAM

QA INSPECTION FORM FOR SS&Ds

Revised July 31, 1997

1. Name and Address of Licensee:

   Theragenics Corporation
   5325 Oakbrook Parkway
   Norcross, GA 30093

   Latitude: _____ Longitude: _____ How obtained:

2. Is licensee: Manufacturer XXX Distributor XXX

3. Licensee Contact: T. Tydings Robin, Jr., Ph.D. Telephone Number: 770-271-6840

4. Certificate Number: GA 645-S-101-S Model: 200 (Old Model 100)

   Date of Last Amendment: June 6, 1988

5. Date of Inspection: October 29, 1997 Date of Previous Inspection: N/A -- initial

6. Type of Inspection: (X) Announced ( ) Unannounced
   ( ) Routine ( ) Special
   (X) Initial ( ) Reinspection

7. Priority: III

8. Next Inspection Date: October 2000 (X) Normal ( ) Reduced ( ) Extended

9. Scope and Summary of Inspection:

   This inspection covered the QA/QC procedures and checks identified in the SS&D registry certificate(s). Verification of these items will confirm if the source(s)/device(s) are being manufactured/distributed as stated in the registration certificate(s).

   This inspection was broken into two portions: (1) production of the Palladium pellets themselves, and (2) assembly of the Palladium seeds. The first portion was conducted at the Buford facility and reviewed the processes of target removal from the block through shipment of the finished pellets to Norcross. The second portion was conducted in Norcross and included a tour of the facility, demonstrating the assembly of the seeds in a step-by-step process up to and including shipment to the licensed end users. Various assembly personnel were observed and interviewed at their stations during the facility tour.

   Issues mentioned in facsimile from Theragenics to RMP dated October 28, 1997 were not addressed.

10. Participants (Include name and title of persons involved):

Eric T. Jameson	GA RMP, Sr. Radiological Health Specialist
Mark Hughes	Theragenics Corp., Manufacturing Manager
Len Owens	Theragenics Corp., Quality Systems Manager
T. Tydings Robin, Jr., Ph.D., LLB	Theragenics Corp., Radiation Safety Officer
Joseph J. Rodgers, M.S.	Theragenics Corp., Senior Health Physicist
Janet E. Zeman	Theragenics Corp., Directory of Regulatory Affairs

11. Management Interview and Inspection Findings (Discuss general inspection findings, overall status of program, individuals involved):

All manufacturing procedures (creation and purification of Pd-103, plating, activity verification) and assembly procedures ("manual" assembly, laser welding, assay) are quality procedures and ensure that TheraSeeds® are manufactured according to specifications. Numerous checks are used during the assembly process to ensure that pellet accountability is maintained.

Ty Robin will share these results with Glen Dill (Director of Operations), who was not able to make the close-out interview. Ty Robin also committed to update the existing registration certificate during the current requested SS&D amendment (change to automated seed assembly process, currently being reviewed by FDA). The existing SS&D registration certificate, dated 1988, lists, among other items, an old address, irradiation of assembled seeds (no longer performed -- use cyclotron instead), and an old maximum activity per source (distribution license amended in 1991).

12. Action and Date: (X) No Violations / Compliance Letter dated: November 5, 1997

( ) Violations / Notice of Violations dated:

( ) Inspection Acknowledgment Form: Clear/Violations

13. Inspector: Eric Jameson Date of Report: November 5, 1997

Eric Jameson

14. QUALITY ASSURANCE OF SOURCE/DEVICE

Does visual inspection match written description? (source/device on site only) . . . . . Yes

Does device contain the proper sources? . . . . . N/A

Is source activity ≤ maximum activity . . . . . Yes *
* refer to Section 11 for caveat

Certificate of Conformance for received sources . . . . . N/A -- do not receive sources

Source has valid leak test . . . . . Yes, after assembly & prior to shipment

Shutter mechanism operates as described (device only) . . . . . N/A

Labeling/identification as described . . . . . Yes
GL label . . . . . N/A

External radiation levels agree (source/device on site only) . . . . . Yes

Transportation documents/user instructions as described . . . . . Yes

Describe QA/QC procedures performed by licensee

pellet production: (1) check for Zn as impurity during extraction/purification phase (if found, refilter and purify); (2) verify at 50/70/90% activity that plating is going at predicted rate (if not, adjust remaining time accordingly); (3) at 100% activity, perform trace element analysis on pellet (looking for high levels of Zn)

seed assembly: (1) receipt of titanium tubes and endcaps from quality-approved supplier; (2) visual verification of cold assembly (before pellets added), pre- and post-weld; (3) visual verification of hot assembly (after pellets added), pre- and post weld; (4) counting of pellets/seeds at each station during assembly; (5) checking of autoclave liquid for contamination (i.e., leak test); (6) counting of seeds before sent to assay; (7) checking for defects via visual inspection under microscope

after seed assembly: send first few seeds to Buford to verify activity; use some to calibrate Capintec dose calibrator, some for trace analysis

15. FOR FOREIGN MANUFACTURED SOURCES AND DEVICES . . . . . N/A

Receipt Documentation complete? . . . . .

Certificate of Conformance . . . . .
Transportation Documentation . . . . .
Valid leak test . . . . .
Receipt Surveys . . . . .
QA/QC verification by manufacturer . . . . .
Third party independent QA/QC, copy of report provided to Division . . . . .

Describe manufacturer's QA/QC procedures

16. **FOR DROP SHIPPED SOURCES AND DEVICES (directly to end user)** . . . . . N/A

Describe QA/QC procedures performed by Field Service Technician