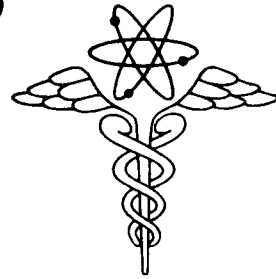


THERAGENICS CORPORATION

900 Atlantic Drive, N.W., Atlanta, Georgia 30318 (404) 894-3609



September 12, 1986

Cynthia A. Sanders
Senior Radiological Health Specialist
Georgia Department of Human Resources
Radioactive Materials Unit, Suite 600
878 Peachtree Street, N.E.
Atlanta, GA 30309

Dear Ms. Sanders,

Thank you for your letter of August 5 transmitting the Review Copy of the Model 100 sealed brachytherapy source safety evaluation and registration. With this letter we enclose amended copies of the draft labels which show the correct Company name, and offer the following comments:

Review Copy Page 4, QUALITY ASSURANCE AND CONTROL, should read "After Completion of Seed Assembly"

Review Copy Page 6, last sentence, Reference (1) was reference to footnote 1 on page 18 of our Submittal, which was as follows:

"Paul V. Harper, K. A. Lathrop; "Palladium-103 as a Therapeutic Radiation Source" Nuclear Medicine (Stuttgart, F.R.G.) 1965, p411."

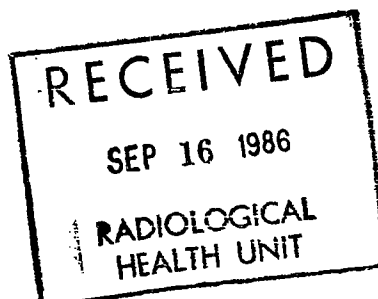
We recommend adding this to the list of References and re-numbering the footnote on page 6 to correspond to it.

Sincerely yours,


Richard A. Moore
Vice President

RAM:jtk


Enclosure



PALLADIUM SEED DRAFT LABELS

Palladium Seeds (Pd-103)	
Radionuclide Brachytherapy Source	
Caution: RADIOACTIVE MATERIAL	
Apparent Activity Range _____	mCi comp
Total Apparent Activity _____	mCi comp
Assay Date _____	Lot _____
No. of Seeds _____	
<small>This Product Made In U.S.A. By: Theragenics Corporation Atlanta, Ga. 30318</small>	

(1) Unbreakable Vial

 THERAGENICS CORPORATION	Palladium Seeds (Pd-103)
Radionuclide Brachytherapy Source Model 100	Apparent Activity Range _____ mCi comp
Description: The Palladium Seeds consist of a Titanium Tube, sealed through the use of Laser welded Titanium end cups. Enclosed are two Palladium 103/Aluminum Rods and a Lead Rod x-ray marker.	Total Apparent Activity This Vial _____ mCi comp
WARNING Licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to §35.14 and §35.100 Group VI of 10 CFR Part 35 or under equivalent	Number of Seeds _____
licenses of Agreement states. CAUTION Federal law restricts this device to sale by or on the order of a physician. Maintain proper radiation safety precautions at all times.	Assay Date _____ Lot No. _____
	Caution: RADIOACTIVE MATERIAL
	<small>See package insert for instructions on handling storage of Palladium Seeds. Made in USA By Theragenics Corporation Atlanta, Ga. 30318</small>

(2) Lead Vial Holder

Palladium Seeds-(Pd-103)

Radionuclide Brachytherapy Source

Total Apparent Activity _____ mCi
comp.

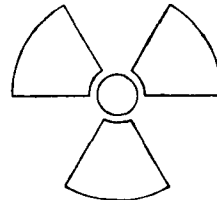
Surface Dose Rate _____ mRem/hr.

Assay Date _____

Total No. Of Vials _____

Total No. Of Seeds _____

This Product
Made In U.S.A. By:
Theragenics Corporation
Atlanta, Ga. 30318.



Caution: RADIOACTIVE MATERIAL

(3) Steel Can

<p>THERAGENICS CORPORATION 900 Atlantic Drive, N.W. - P.O. Box 94085 Atlanta, Georgia 30318</p> <hr/> <p>TO</p>
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(4) Shipping Box