



AFFIDAVIT

**RE: Attachments to Letter Dated August 13, 1999 – TheraSphere Application for
USNRC sealed Source and Device Registration**

I, E.S. Martell, in my capacity as Vice-President, Quality and Regulatory Affairs, having been duly authorized to apply for withholding of disclosure of proprietary information by and on behalf of MDS Nordion Inc., do depose and say:

1. I, E.S. Martell, am the Vice-President, Quality and Regulatory Affairs and Operations Services of MDS Nordion Inc.
2. Information contained in the following specification documents is proprietary to MDS Nordion Inc:

990601.SPE YAS Glass Frit
990602.SPE Yttrium-89 Microspheres
3. MDS Nordion believes that information contained in specification documents pertaining to TheraSphere is proprietary and would be of benefit to competitors if made public
4. This information is held in confidence by MDS Nordion Inc. and any disclosure thereof for developmental purposes, has been accompanied by a confidentiality agreement protecting the trade secrets contained therein.
5. This information has been transmitted to and received by the Nuclear Regulatory Commission in the United States in confidence.

A handwritten signature in black ink, appearing to read "E. Martell", is written over a horizontal line.

E.S. Martell
Vice-President, Quality Assurance and Regulatory Affairs

SWORN BEFORE ME THIS 30th
DAY OF SEPTEMBER, 1999
IN THE CITY OF KANATA, IN
THE PROVINCE OF ONTARIO.

A handwritten signature in black ink, appearing to read "Neil Gotfrit", is written over a horizontal line.

Neil Gotfrit, Notary Public

487 Minto Road
Kawata, Ontario
Canada K2K 1X8
Tel: (613) 592-2790



Science Advancing Health

September 29, 1999

John Jankovich
Sealed Source Section
Division of Nuclear Materials Safety and Safeguard
U.S. Nuclear Regulatory Commission
Mail Stop: T8F-5 White Flint North
11545 Rockville Pike
Rockville, MD
20555

Dear Mr. Yankovich;

RE: Request for Withdrawal of Documents from Public Disclosure further to Device Approval Application for TheraSphere

In accordance with 10 CFR Part 2.79, this is to inform you of a request for withdrawal of documents from public disclosure in support of the application for device approval of TheraSphere. These documents are specifications 990601.SPE and 990602.SPE. An affidavit statement is attached.

The reason for the requests for non-public disclosure of the documents is that they contain information that would be of benefit to competitors if made public.

If you require more information or more detail please do not hesitate to contact me.

Yours sincerely,

A handwritten signature in cursive script, appearing to read 'Ann Warbick Cerone'.

Ann Warbick Cerone
Manager, Regulatory Affairs
Tel: (613) 592-3400 Ext. 2033
Fax: (613) 591-7481

147 Birch Road
Kanata, Ontario
Canada K2K 1X8
Tel: 613 592-2790



Science Advancing Health

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