February 15, 2000

Ms. Ann Warbick Cerone
Manager, Regulatory Affairs
MDS Nordion
447 March Road
Kanata, Ontario, Canada K2K 1X8

Dear Ms. Cerone:

Based on the information and test data submitted in your application dated July 2, 1999, and subsequent correspondence, we conclude the Model TheraSphere therapeutic device is acceptable for licensing purposes in accordance with the conditions of the enclosed registration certificate (NR-0220-D-113-S).

Please be advised that you must manufacture and distribute the product in accordance with the statements and representations contained in your application, with enclosures thereto, and the information set out in your registration certificate. As a general rule, you must request and obtain an amendment to the certificate before you make changes or modifications to the information submitted to obtain the certificate.

Please read over the registration certificate in its entirety and notify us immediately of any errors or omissions.

You are obligated to notify us promptly in writing should you decide to no longer manufacture or offer service support for the product.

Please be aware that, as a holder of an NRC registration, you may be subject to the NRC's licensing fees in accordance with 10 CFR Part 170, and annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the License Fee and Debt Collection Branch at (301) 415-6096.

If you have any questions, please contact me at (301) 415-7904 or Dr. Seung Lee at (301) 415-5787.

Sincerely,

original signed by:
John P. Jankovich, Ph.D., Sr. Engineer
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety
And Safeguards

Enclosure: As stated
cc w/encl: SKimberley, LFDCB
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