

February 14, 2000

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

Dear Ms. Cerone:

In your letter dated February 2, 2000, you requested that we return Attachments 1 to 8 which had been attached to your letter of January 14, 2000. We understand that the Attachments consisted of proprietary drawings and we determined that the NRC does not need these drawings to perform a safety evaluation of your application for registration of your Model TeleSphere therapeutic device. Therefore, we return the Attachments as listed below and we accept, as replacement, the drawing which had been attached to your letter dated February 2, 2000.

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

Sincerely,

/s/
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:

- Attachment 1- MDS Nordion Drawing No. K120612-003
- Attachment 2- MDS Nordion Drawing No. K120612-004
- Attachment 3- MDS Nordion Drawing No. K120612-005
- Attachment 1- MDS Nordion Drawing No. K120612-006
- Attachment 5 - MDS Nordion Drawing No. F139001-003
- Attachment 6 - MDS Nordion Drawing No. F139001-004
- Attachment 7 - MDS Nordion Drawing No. F139001-005
- Attachment 8 - TheraSphere Shipping Package Information Drawing

Distribution:

IMNS r/f SSD-00-04 SSD-99-44 NE01 *JK*

SSD File # NR-0220-D-113-S

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| NAME | Jjankovich/jj | | SLee <i>SL</i> | | | | | |
| DATE | 2/11/00 | | 2/11/00 | | | | | |

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OFFICIAL RECORD COPY

CONVERSATION RECORD

TYPE:

Outgoing Telephone x
Incoming Telephone
Meeting

NAME OF PERSON CONTACTED:

Ann Warbick Cerone

ORGANIZATION:

MDS Nordion

TIME:

2:30 pm

DATE:

02/14/0

SUBJECT:

Solubility of Adhesive Model E117, used on labels

SUMMARY:

I called Ms. Cerone to clarify the statement in Paragraph 4, page 2, of MDS Nordion's letter dated January 19, 2000 regarding the adhesive Model E117. The letter stated that the adhesive is water based acrylic. Ms. Cerone stated that the term "water based" refers to the manufacturing process, it does not mean that the adhesive is soluble in water. She said that the adhesive is not soluble in water.

ACTION REQUIRED:

NRC to proceed with the review of the application.

PLACE THIS RECORD IN:

Registration File NR-0220-D-113-S
QA File
Incident File
General File SSD 00-04

PERSON DOCUMENTING THE CONVERSATION:

John Jankovich

SIGNATURE:**DATE:**

02/14/0