



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

WASHINGTON, D.C. 20555-0001
October 26, 1999

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

**SUBJECT: REQUEST FOR WITHHOLDING INFORMATION FROM PUBLIC DISCLOSURE,
MDS NORDION INC. MODEL THERASPHERE DEVICE**

Dear Ms. Cerone:

By MDS Nordion Inc.'s (Nordion's) application dated July 2, 1999, your letter dated September 29, 1999, and an affidavit, executed by E. S. Martell, dated September 30, 1999, Nordion submitted an application for registration of the Model TheraSphere microspheres. Nordion has requested that two test procedures, No. 990601.SPE, entitled "YAS Glass Frit," and No. 990602.SPE, entitled "Yttrium-89 Microspheres," be withheld from public disclosure pursuant to 10 CFR 2.790.

Nordion stated that these test procedures should be considered exempt from mandatory public disclosure for the following reasons:

1. The disclosure of the information contained in the procedures would cause irreparable harm to Nordion. In particular, these procedures contain information, developed by Nordion with Nordion's resources regarding specifications such as acceptance/rejection tolerances for materials used in the production of the microspheres.
2. The information is not available in public sources.

We have reviewed Nordion's application and the test procedures in accordance with the requirements of 10 CFR 2.790 and, on the basis of your statements, have determined that the submitted information sought to be withheld contains proprietary commercial information.

Therefore, Procedure Nos. 990601.SPE and 990602.SPE of the submitted information, listed as proprietary, will be withheld from public disclosure pursuant to 10 CFR 2.790(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended.

Ms. Cerone

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Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will, of course, ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, you should promptly notify the NRC. You also should understand that the NRC may have cause to review this determination in the future, for example, if the scope of a Freedom of Information Act request includes your information. In all review situations, if the NRC makes a determination adverse to the above, you will be notified in advance of any public disclosure.

Sincerely,

JS

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

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