447 March Road
Kanata, Ontario
Canada K2K 1X8
Tel: 613 592-2790

MDS Nordion
Science Advancing Health

December 17, 1999

John T. Yankovich
Senior Engineer
Sealed Source Safety Section
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Materials Safety and Safeguard
United Stated Nuclear Regulatory Commission
Mail Stop: T-8F-5
2 White Flint North
11545 Rockville Pike
Rockville, MD
20555

Dear Mr. Yankovich:

RE: TheraSphere Application for USNRC Sealed Source and Device Registration

Enclosed please find a copy of the United States Food and Drug Administration approval letter for the Humanitarian Device Exemption (HDE) Application for TheraSphere.

If further clarification is required please contact me.

Yours sincerely,

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 1999

James Goin, Ph.D.
U.S. Representative for MDS Nordion, Inc.
c/o DataMedix Corporation
600 North Jackson Street, Suite 306
Media, Pennsylvania 19063

RECEIVED
DEC 13 1999
REGULATORY AFFAIRS

Re: H980006
TheraSphere®
Filed: August 11, 1998
Amended: September 14 and December 31, 1998; March 19 and April 8, 1999

Dear Dr. Goin:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your humanitarian device exemption (HDE) application for TheraSphere®. This device is indicated for radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable hepatocellular carcinoma (HCC) who can have placement of appropriately positioned hepatic arterial catheters. CDRH is pleased to inform you that your HDE is approved subject to the enclosed "Conditions of Approval." You may begin commercial distribution of the device after you have submitted an amendment to this HDE with copies of the approved labeling in final printed form.

The sale, distribution and use of this device are limited to prescription use in accordance with 21 CFR 801.109.

FDA wishes to remind you that failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

CDRH will notify the public of its decision to approve your HDE by making available a summary of the safety and probable benefit of the device upon which the approval was based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/ode/hdeinfo.html. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the HDE number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Any information to be submitted to FDA regarding this HDE should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above HDE number to facilitate processing:

Document Mail Center (HFZ-401)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact John C. Monahan at (301) 594-1212.

Sincerely yours,

Kimber C. Richter

Kimber C. Richter, M.D.
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure