

**From:** "WARBICK CERONE, Ann (Kanata)" <AWARBICK@MDS.Nordion.com>  
**To:** "John Jankovich (E-mail)" <jpj2@nrc.gov>  
**Date:** Wed, May 17, 2000 3:36 PM  
**Subject:** Corrected: Expiry: 7 days after calibration

<<TheraSphere-labels-draft-May2000.doc>>

Thank you for your consideration and assistance.

Ann

Lead Pot / Product Label

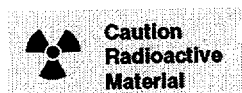
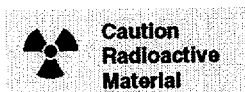
# TheraSphere®

## YTTRIUM-90 GLASS MICROSPHERES INJECTION

**Lot** 999999**Cal. Date** 1999-JA-01 000:00 h ET**Exp.** 7 days after calibration**Contains:** 50 µl H<sub>2</sub>O**Activity** 5 GBq (135 mCi)**Microsphere** 45 mg**Sp. Act.** 0.11 GBq/mg (3 mCi/mg)**See package insert for directions for use.**

Humanitarian device authorized by federal (USA) law for use in radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable hepatocellular carcinoma who can have placement of appropriately positioned hepatic arterial catheters.

The U.S. Nuclear Regulatory Commission has approved the distribution of TheraSphere® to persons licensed to use byproduct material identified in §§ 35.57, 35.400 and 35.500, as appropriate, and to persons who hold an equivalent license issued by an Agreement State.

**447 March Rd., Kanata, Ontario, Canada K2K 1X8**

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Administration Set Label

# TheraSphere®

## Administration Set

For use in the administration of TheraSphere® (Y-90 microspheres) only.  
See package insert for directions of use.

**Lot Number:** M0000

**Expiry Date:** 1999-JA-01

Humanitarian device authorized by federal (USA) law for use in radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable hepatocellular carcinoma who can have placement of appropriately positioned hepatic arterial catheters.

Manufactured for



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for <jpj2@nrc.gov>; Wed, 17 May 2000 15:39:55 -0400 (EDT)  
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From: "WARBICK CERONE, Ann (Kanata)" <AWARBICK@MDS.Nordion.com>  
To: "John Jankovich (E-mail)" <jpj2@nrc.gov>  
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