



October 4, 2006

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

Br. 2

2006 OCT 10 AM 9:54

RECEIVED
REGION 1

Re: Additional Marketing Label

Dear License Assistance Team

I have spoken with John Nicholson of the NRC and he indicated that I should advise the Licensing Division that Advanced Care Medical intends to add a "Marketed by BrachySciences" additional label to several of our licensed, sealed source, stranded for loose configuration products.

The Distribution License for Advanced Care Medical is 06-30764-02 Amendment 8, (02/10/06).

MD ^{RLS}
03036179

The label we intend to use will appear below our standard Advanced Care Medical product labeling or will be placed on the reverse side of the sterile product pouch. It will be a "marketing label" not a product label and will serve to differentiate orders that are received from BrachySciences for shipment to licensed facilities.

Advanced Care Medical will continue to use all the current labels on both the exterior shipping box and interior individual product packages.

The Food and Drug Administration was advised May 12, 2005 that BrachySciences was located at the same 115 Hurley Road, Oxford CT address and shares the same facility registration number as WorldWide Medical Technologies and Advanced Care Medical (12251140).

Please contact me if you have any questions about this request.

Sincerely,

Wayne W. Richardson
Radiation Safety Officer
Advanced Care Medical
Director of Quality, Regulatory Affairs
WorldWide Medical Technologies
115 Hurley Road, Bldg. 3A
Oxford, CT 06478

115 HURLEY ROAD OXFORD, CT 06478
TEL: 203.262.4194 FAX: 203.262.4193

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NMSS/RGNI MATERIALS-002

This is to acknowledge the receipt of your letter/application dated

10/4/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 06-30764-02MD There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 139518.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.