



# Nucletron

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February 15, 2002

Ms. Ray Manley  
Maryland Department of the Environment  
Radiological Health Program  
2500 Broening Highway  
Baltimore, MD 21224

COPY

**RE: Clarification for Proposed Source Label Amendment Request  
MD-497-D-108-S  
microSelectron HDR (105.999)**

Dear Mr. Manley:

This correspondence serves to clarify the amendment request dated December 27, 2001. The amendment proposed a new source label. The source label is attached to the treatment unit after a new source is installed. First and foremost, there has been no change in source design or manufacture. The same source will be used. Nucletron, however, does want to change the model number for the source from DRN7736 to 105.002. The DRN7736 model number is the identifier used by Mallinckrodt. The 105.002 number is the design version identifier used by Nucletron. The second paragraph on page 2 of the December correspondence may have been confusing. The paragraph intended to point out that the SS&D application for the V2 was re-submitted in its entirety October, 2001 and that the source model number changes were included in that submittal but not emphasized.

Second, the amendment request addressed both cardboard labels and adhesive labels. Once Mallinckrodt begins providing the labels with the source, the labels will be of an adhesive type. The label will look just like the cardboard labels that were provided to MDE in the December correspondence, but, the back side will be sticky. It is expected that the adhesive labels will be available in May 2002. Until the adhesive label is available Nucletron wants to use a cardboard version and attach it the same way the label has always been attached, using a clear plastic business card holder. The proposed label is improved, provides consistency in labeling among Nucletron's different model afterloaders and meets other global requirements.

Page 2  
Mr. Manley

If you have any questions regarding the above matter, please contact the undersigned at 410-872-4435.

Sincerely,

Lisa Cole Dimmick  
Director of Regulatory Affairs

Enclosure: December 27, 2001 letter for reference