



# Washington University in St. Louis

## SCHOOL OF MEDICINE

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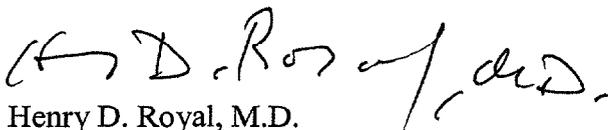
Docket No. 2004N-0432  
Division of Dockets Management (HFA-305)  
US Food and Drug Administration  
5630 Fishers Lane – Rm. 1061  
Rockville, MD 20852

Dear Sir:

I attended the 11/16/04 public meeting on radioactive drug research committees. I am writing to express my concern over the January 16, 2005 deadline for comments on the RDRC meeting on "Radioactive Drugs for Certain Research Uses". It came to light at the November 16 public meeting that the Food and Drug Administration (FDA) expects to issue a "Screening IND Guidance Draft" within that same timeframe. Since (as was pointed out at the RDRC session) that Guidance document could materially affect the RDRC issues under discussion, it is imperative the January 16 deadline be extended. A prudent extension would probably be 6 weeks to 2 months after the Guidance document is issued.

The RDRC pathway has provided a very valuable, safe and cost-effective mechanism to carry out early studies of radiopharmaceuticals.

Sincerely,

  
Henry D. Royal, M.D.

cc: Dr. George Mills  
US Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Division of Medical Imaging (HFD-160)  
5600 Fishers Lane  
Rockville, MD 20852

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