

December 8, 2004

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

Department of
Radiology

PET Imaging
Science Center

Dear Sir:

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 Draft is issued.

I expect to submit additional comments regarding the other issues raised at the RDRC meeting as I have had the opportunity to review the Guidance Draft, and thank the FDA for organizing this important session.

Sincerely,



Peter S. Conti, MD, PhD, FACR, FACNP
Professor of Radiology, Biomedical Engineering and
Clinical Pharmacy
Director USC PET Center

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

2004 N-0432

EXT 4