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March 30, 2005

U.S. Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

IR 2005001

**Re: Reply to a Notice of Violation,  
License No. 41-30557-01, Docket No. 03035323**

Dear Mr. Dwyer,

During your telephone interview on February 3 and 4, 2005 of the PETNET Pharmaceuticals, Inc., North Wales, Pennsylvania site, the following Severity Level IV violations were noted:

- A. Condition 11 of License No. 41-30557-01 requires that the Radiation Safety Officer for this license is Lory Hansen, R.Ph., Ph.D.

Contrary to the above, between May 2004 and February 3, 2005, the Radiation Safety Officer for this license was not Lory Hansen, R.Ph., Ph.D. Specifically, Dr. Hansen left the employ of the licensee in May 2004 and the licensee did not request amendment of the license to name a new Radiation Safety Officer until February 3, 2005.

- B. Condition 12 of License No. 41-30557-01 requires that licensed material be used by, or under the supervision of, Lory Hansen, R.Ph., Ph.D.

Contrary to the above, between May 2004 and February 3, 2005, licensed material was not used by, or under the supervision of Lory Hansen, R.Ph., Ph.D. Specifically, Dr. Hansen left the employ of the licensee in May 2004 and the licensee did not request amendment of the license to name a new Radiation Safety Officer until February 3, 2005.

This issue was identified during an audit of the facility, conducted by the corporate Radiological Compliance Department (RCD), on May 3, 2004 and in a follow up on September 2, 2004. This was handed off to our licensing specialist to submit the appropriate amendments. Unfortunately, there was no follow up on this audit report and, due to the high workload in the RCD, the amendment was not submitted in a timely fashion. We apologize for this inadvertent oversight on our part. To prevent a recurrence of a failure to follow up on an audit deficiency, the RCD has developed an audit tracking database. This database will be used to track all deficiencies identified during an RCD audit, and includes provisions to actively notify RCD and pharmacy staff, via email, when due dates approach. I would like to assure you that PETNET management takes these kinds of license violations very seriously and would like to emphasize that there will be close monitoring of the regulatory compliance program by the corporate staff. Our objective at PETNET Pharmaceuticals, Inc. is to comply with the rules and regulations at all of our facilities and to ensure the health and safety of our employees, patients and the public.

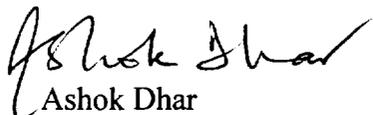
We would also like to apologize for not submitting this response within 30 days of receipt of the Notice of Violation. We have had additional personnel changes at the facility and the NOV was

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not sent to our corporate office for action. As of March 2005, Mr. Durkin has left the company. Barbara Missal RPh, BCNP, is acting as the interim Radiation Safety Officer. An amendment to the license naming her as RSO and authorized user was submitted to your office on March 24, 2005.

If you have any questions, please do not hesitate to call either myself or Tracy Gale, Northeast Regional Health Physicist.

Sincerely,



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Corporate RSO  
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