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March 23, 2005

Steven Courtemanche  
Nuclear Materials Section branch 1  
Division of Nuclear Materials Safety  
Region 1  
475 Allendale Road  
King of Prussia, PA 19406-1415

RECEIVED  
REGION 1  
MAR 24 11:57 AM '05

Re: PETNET Pharmaceuticals North Wales, PA Facility, NRC Materials License # 41-30557-01

03035323

Dear Mr. Courtemanche,

The purpose for this letter is to request an amendment for PETNET Pharmaceuticals North Wales, PA facility (Materials License # 41-30557-01).

Specifically it is requested that the following items be amended to our license:

1. We request that Barbara Missal, BCNP and Matthew Mauro be added to license condition 12 of our license as an authorized user. Ms. Missal was previously listed as an authorized user on NRC materials license number 37-30722-01MD (Medi-Physics). Mr. Mauro was previously listed on NRC materials license number 24-04206-17MD (Mallinckrodt).
2. We also request that the Radiation Safety Officer (RSO) be changed from Robert Durkin to Barbara Missal, per License Condition 11 of our materials license (License # 41-30557-01). Ms. Missal was previously the RSO for NRC materials license number 37-30722-01MD. Also, Ms. Missal meets the RSO qualifications per NUREG – 1556 Vol. 13, *NRC's Consolidated Guidance About Materials Licenses Program-Specific Guidance About Commercial Radiopharmacy Licenses* which states that: Any individual who has sufficient training and experience to be named as an authorized nuclear pharmacist (ANP) is also considered qualified to serve as the facility RSO.
3. We also request that Robert Durkin be removed from license condition 12 of our NRC materials license as an Authorized User. Mr. Durkin is no longer working for PETNET's North Wales, PA facility.

136762

NMSS/RONI MATERIALS-002

We trust that this information is sufficient for you to grant the requested license amendment. If you have any additional questions, please contact me at the number below, or Duane White at 865-218-3239.

Sincerely,



Ashok Dhar  
Senior Director, Regulatory Management  
Corporate RSO  
PETNET Pharmaceuticals Inc.  
E-mail: [ashok.dhar@petnetpharmaceutical.com](mailto:ashok.dhar@petnetpharmaceutical.com)  
Voice: 865-218-2593  
Fax: 865-218-3018

Cc: Barbara Missal  
Facility Manager  
PETNET Pharmaceuticals Inc.  
North Wales, PA

Duane White  
Regional Health Physicist  
PETNET Pharmaceuticals, Inc  
Knoxville, TN

Tracy Gale  
Regional Health Physicist  
PETNET Pharmaceuticals Inc.  
Northeast Region

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

3/23/2005, and to inform you that the initial processing which includes an administrative review has been performed.

AMCND. 41-30557-01  
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

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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** 136762.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

(FOR LFMS USE)  
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

: Program Code: 03124  
: Status Code: 0  
: Fee Category: 3P  
: Exp. Date: 20100430  
: Fee Comments: \_\_\_\_\_  
: Decom Fin Assur Req'd: N  
: ::

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: P.E.T. NET PHARMACEUTICALS ,INC  
Received Date: 20050325  
Docket No: 3035323  
Control No.: 136762  
License No.: 41-30557-01  
Action Type: Amendment

2. FEE ATTACHED

Amount:           /            
Check No.:           /          

3. COMMENTS

Signed           M. A. Perkins            
Date           4/14/2005          

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /\_/\_/)

1. Fee Category and Amount: \_\_\_\_\_

2. Correct Fee Paid. Application may be processed for:

Amendment \_\_\_\_\_  
Renewal \_\_\_\_\_  
License \_\_\_\_\_

3. OTHER \_\_\_\_\_  
\_\_\_\_\_

Signed \_\_\_\_\_  
Date \_\_\_\_\_