



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 17, 2007

Docket No. 03032974  
Control No. 140337

License No. 45-25221-01MD

Mark Soffing  
Corporate RSO  
IBA Molecular North America, Inc.  
100 Executive Drive, Suite 100  
Sterling, VA 20166

**SUBJECT: IBA MOLECULAR NORTH AMERICA, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 140337**

Dear Mr. Soffing:

This is in reference to your letter dated March 30, 2007 requesting to amend Nuclear Regulatory Commission License No. 45-25221-01MD. In order to continue our review, we need the following additional information:

1. Certain experience elements as required by 10 CFR 35.55(b)(1)(ii) were not included in the attestation statement by Earnest Samuel for Darren J. Patti. These experience elements are: Using administrative controls to avoid medical events in the administration of byproduct material; and Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures.
2. 10 CFR 32.72(b)(2)(ii) states, in part, that a pharmacist may work as an authorized nuclear pharmacist if the individual meets the requirements specified in 10 CFR 35.55(b). Please provide the following documentation of training and experience for Shannon Lee Pratschler:
  - a. 700 hours in a structured educational program consisting of both didactic training and supervised practical experience in a nuclear pharmacy in the subjects identified in 10 CFR 35.55(b)(1).
  - b. Written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the training and experience requirements in 10 CFR 35.55(b)(1), and that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

M. Soffing  
IBA Molecular North America, Inc.

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NRC Form 313A (ANP) (enclosed) may be used to document this information. Please note that if the training and experience was received more than 7 years ago, evidence of recentness of training in accordance with 10 CFR 35.59 must also be submitted. Please note that non-agreement state licenses and Cardinal Health's list of approved ANP's are not acceptable forms of documentation.

3. Certain experience elements as required by 10 CFR 35.55(b)(1)(ii) were not included in the attestation statement by Earnest Samuel for Michael C. Tingler. These experience elements are: Using administrative controls to avoid medical events in the administration of byproduct material; and Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material**; then **Toolkit Index Page**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 140337. If you have any technical questions regarding this deficiency letter, please call Dennis Lawyer at (610) 337-5366.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

***Original signed by Thomas K. Thompson***

Thomas K. Thompson  
Senior Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

Enclosure:  
NRC Form 313A (ANP)

DOCUMENT NAME: C:\FileNet\ML071080074.wpd

**SUNSI Review Complete: DLawyer**

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