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

November 14, 2008

Docket No. 03032974 License No. 45-25221-01MD
Control No. 142856

Duann Vanderslice, R.Ph.
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. 142856

Dear Ms. Vanderslice:

This is in reference to your letters dated September 29, 2008 and October 1, 2008 requesting to amend Nuclear Regulatory Commission License No. 45-25221-01MD. In order to continue our review, we need the following additional information:

1. You requested that we remove the word “byproduct” material throughout the license, because the definition of byproduct material was changed to incorporate the materials you are requesting, we continue to use the term “byproduct material” on your license. If you have material that you believer are not defined by the word “byproduct material”, then please request that additional material.

2. For item 6.A., you have requested materials with atomic numbers 1 through 84. Our guidance specifies material with atomic numbers 1 through 83. Confirm that you need atomic number 84. Also, specify the maximum amount of material requested per radionuclide for your byproduct material atomic numbers 1 through 83 request.

3. You specified in your “Radioactive Material and Uses” table that “Any radionuclide with atomic numbers 1 to 84,” is to be in the form of “Any form-except sealed sources.” Please confirm that you wish to change item 7.A. of your license to “Any –except sealed sources.”

4. You requested to delete Material Items 6.F. (31.11(a) materials) and 6.G. (manual brachytherapy sources) on your current license. Removal of these items from your license also removes the authorized use in 9.F. (redistribution to specific and general licensees) and 9.G. (redistribution of sealed sources). Please confirm that you will not distribute RIA kits or brachytherapy sources.

5. You have requested to distribute cobalt 57 sealed sources. Please submit the manufacturer and model number as registered with in the Sealed Source Registry , the sources that you wish to distribute.

6. You have requested Rubidium Generators as one line item that contains all three isotopes. However, this is contrary to our guidance as written in NUREG-1556, Volume 13, Revision 1, "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Commercial Radiopharmacy Licenses." Please request the amount of material you need for each isotope.

7. You requested the authorized use of "research and development as defined in 10 CFR 30.4" for items 6.A., 6.E., and 6.F. This is an unusual request for a radiopharmacy. Please describe the type of research and development that is planned and supporting radiological safety practices not already committed by current licensing applications. Please note that human use research is not covered by this authorization.

8. You requested additional types of radioactive drugs to be distributed. For each additional radioactive drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package):

   a. Indicate the radionuclide and the maximum activity for each type of container (e.g., vial, syringe);

   b. Describe the type and thickness of the "transport radiation shield" provided for each type of container; and

   c. Indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.

9. Please provide your email address.

10. You requested to manufacture radiionuclides using an accelerator at your Missouri location. In accordance with the guidance in NUREG-1556, Volume 21, a separate license is required for the production of radioactive material using an accelerator. The 12 month waiver to request a new licensee does not expire until September 2009. You must submit your request for a new license for production of radioactive materials using an accelerator before the waiver end using the guidance in NUREG-1556, Volume 12. Some additional information that NUREG-1556, Volume 12 requires that was not submitted is:

    a. The amount of material seems high. Please submit documentation that justifies the amount of material in your request.

    b. For the addition of incidental activated products, you have requested for any material with atomic number 1 through 84. Please confirm that you desire atomic number 84. Please specify the maximum amount of material requested per radionuclide for your byproduct material atomic number 1 through 83 request.

c. Describe the facilities and equipment associated with the cyclotron where radioactive material will be produced, possessed, and/or used. Include the following information:

i. A description and diagrams that show the locations of delivery lines, shielded areas and equipment (e.g., hot cells, waste), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety ;

ii. A diagram and a description of the ventilation system, including representative equipment such as hot cells, glove boxes, or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne; and

iii. Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d). See Regulatory Guide 4.20, “Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors,” for guidance on methods that are acceptable to the NRC.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications.** You may also 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 8:00 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. 142856. 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 Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

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