Dear Mr. Palmer

This is in reference to your letter dated May 11, 2012 requesting to amend Nuclear Regulatory Commission License No. 47-25375-01MD. In order to continue our review, we need the following additional information:

 You have requested that Teresa Tribe be named Radiation Safety Officer (RSO) on your license. It appears that this individual is authorized and works as an authorized nuclear pharmacist on another NRC license. Please confirm if this person will be a full time employee of Pharmalogic or if this individual will act as a consultant-RSO. If Ms. Tribe will not be a full time employee of Pharmalogic, in support of this request, please address the following:

a. Describe the control over the radiation safety program that will be delegated so that the RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

b. Describe the relationship that will exist between the RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.

c. Identify other commitments of the RSO for other NRC or Agreement State licensed facilities, along with a description of how the RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the RSO's minimum amount of on-site time (hours per week).

d. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

e. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

- 2. You requested to add Benjamin Collins, RPh as an Authorized Nuclear Pharmacists. To support this request, please provide the pharmacists' license number and issuing entity.
- You are listed as the licensee management contact in our records. As the management contact, you are authorized to sign correspondence with the NRC. Please confirm if you will remain the contact person. If not, please provide name, address, telephone number, and e-mail for the contact person.

Current NRC regulations and guidance are included on the NRC's website at <u>www.nrc.gov</u>; 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 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 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. 577599. Please respond to this RAI in a hard copy letter, a fax copy of a letter, or a pdf of a signed hard copy response. We cannot accept a response by email alone. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5143.

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

Sincerely,

Farrah C. Gaskins Health Physicist U.S. NRC, Region 1 2100 Renaissance Blvd, Suite 100 King of Prussia, PA 19406 (610) 337-5143 office (610) 337-5269 fax