From:	Lawyer, Dennis
To:	Moore, Jerry (NIH/NCI) [C] (moorejerry@mail.nih.gov)
Subject:	Leidos Biomedical Reseearch, Inc., Request for Additional Information Concerning Application for a License Amendment, Control 610324
Date:	Tuesday, November 27, 2018 6:45:00 AM

Dear Mr. J.T. Moore,

This is in reference to your letter dated October 31, 2018, and Dr. George Afari's letter dated October 18, 2018, for amendment to Nuclear Regulatory Commission License No. 19-21091-01, Docket No. 03019755. It is our understanding that the only authorized nuclear pharmacist has left your employment and that the radiopharmacy has stopped producing manufactured drugs. In addition, the state has withdrawn its pharmacy waiver and thus no longer licensed by the state as a pharmacy. These letters affect the commitments which authorized License Condition 13. This License Condition authorizes you, a broadscope licensee, to manufacture drugs containing radioactive material for non-commercial distribution to specific licensees. Broadscope licensees require specific authorization to manufacturer drugs as stated in 10 CFR 33.17(a)(4).

Based on your letter, it appears that you wish to produce drugs for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA. In order for this to be used as material for medical use, a medical licensee, authorized to perform uptake, dilution, excretion, imaging and localization studies under 10 CFR 35.100 or 35.200 must receive the material. The amount of material must be less than the amount that requires a written directive as stated in 10 CFR 35.40(b). In order to continue our review, we need the following additional information:

Please confirm if our understanding is correct and that you will:

A) only transfer manufactured drugs to medical licensee's for research who are authorized to perform studies under 10 CFR 35.100 and 35.200;
B) the drugs are manufactured in accordance with an Investigational New Drug (IND) protocol accepted by FDA; and
C) the dosage level will be less than the amount that require a written directive as stated in 10 CFR 35.40(b).

We will continue our review upon receipt of this information. Please reply to my attention at the Region 1 Office (Address below) and refer to Mail Control No. 610304. If you have technical questions regarding this letter, please call me at (610) 337-5366.

Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email; or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. 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 OR amendment request.

Please respond by e-mail to acknowledge that you have received the e-mail request for additional information.

Region 1 Office Mailing Address: Licensing Assistance Team, US Nuclear Regulatory Commission Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406-

2713.

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