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

May 25, 2011

Docket No. 03038452 License No. 31-31441-01
Control No. 575181

Robert J. Aiello, Ph.D.
Senior Director of Biology
Karos Pharmaceuticals, Inc.
7 Times Square
New York, NY 10036

SUBJECT: KAROS PHARMACEUTICALS, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 575181

Dear Dr. Aiello:

This is in reference to your application dated May 16, 2011 applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. The management contact on this application, the certifying officer, is you. Please provide contact telephone number, facsimile number and electronic mailing address for our records so we may contact you if needed in the future.

2. On the application, the Radiation Safety Officer was not specified. Please confirm that you will be the Radiation Safety Officer.

3. In section 8 of your application, you specified that you would be in compliance with 10 CFR 19.12. Although the regulations do not require training unless they obtain greater than 100 mRem in a year, it would be inappropriate to allow personnel to handle materials without some proper training. Please commit to the amount of training and the period that personnel will be retrained.

4. You have designated Patricia-Ann Bourassa as an authorized user. (Please note there is no allowance for an Alternate AU on the license. They are either an authorized user or they are not listed.) Please provide the isotopes and quantities of material that she has handled in her experience.

5. In section 8 of your application, you make a statement of the requirements for an authorized user. Please note that for this license type, the authorized users are listed on the license. Only those listed on the license can serve as authorized users and you must apply for an amendment for changes to those authorized users. You do not need to respond to this item.

6. On page 5 of your application, you state that the internal standards to your liquid scintillation machine are exempt from licensing requirements. Most liquid scintillation machine sources are generally licensed and require the user to follow 10 CFR 31.5 requirements associated with these sources. Generally license sources would not be listed on a specific license in which you are applying. You do not need to respond to this item.

7. On page 9 of your application, you list the procedure for Safely Opening Packages Containing License Materials. This page seems to have an error in that it lists the General Topics for Safe Use of Radioisotopes (NUREG-1556, Volume 7, Appendix P) as part of the procedure and not separate from it. Please clarify this page.

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 1-866-512-1800. 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. 575181. If you have any technical questions regarding this deficiency letter, please call me 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 Dennis R. Lawyer

Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

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SUNSI Review Complete: DLawyer

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