



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

August 15, 2013

Docket No. 03035971
Control No. 581503

License No. 06-30726-01

Erin M. Duffy, Ph.D.
Chief Scientific Officer
Rib-X Pharmaceuticals, Inc.
300 George Street, Suite 301
New Haven, CT 06511

SUBJECT: RIB-X PHARMACEUTICALS, INC.; REQUEST FOR ADDITIONAL
INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO
LICENSE; CONTROL NO. 581503

Dear Dr. Duffy:

This is in reference to your letter dated August 5, 2013 requesting to amend Nuclear Regulatory Commission License No. 06-30726-01. In order to continue our review, we need the following additional information:

1. You have requested that K. Paul Steinmeyer be named Radiation Safety Officer (RSO) on your license. In your letter, you stated that this individual is an outside consultant\contractor. 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 consultant-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 consultant-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 consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-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.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. 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 8:00 a.m. to 5:30 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. 581503. 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 letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Farrah C. Gaskins

Farrah C. Gaskins
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Joseph A. Ippolito, Ph.D., Radiation Safety Officer

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SUNSI Review Complete: FGaskins

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