



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

April 27, 2004

Docket No. 03036545
Control No. 134787

License No. 29-30906-01

Maxwell Stock
Vice President
Signum Biosciences, Inc.
1 Deer Park Drive
Monmouth Junction, NJ 08882

SUBJECT: SIGNUM BIOSCIENCES, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 134787

Dear Mr. Stock:

This is in reference to your application dated March 30, 2004 applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. Your application does not contain the information needed to support your request for a research and development license of limited scope. Please resubmit your application using the guidance in NUREG-1556, Volume 7, December 1999 "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope" (enclosed). The checklist in Appendix C in NUREG-1556, Volume 7 contains procedures that are acceptable to the NRC and may be used to submit your response. You may photocopy Appendix C and check the appropriate responses. Please use the suggested responses in Appendix C and attach a description when requested. Please do not include information not requested in Appendix C such as your radioactive package receipt survey procedure and forms, removable contamination survey procedure or emergency procedures.
2. You have requested that Vadim Smirnov be named as the Radiation Safety Officer (RSO) for your license. Section 8.7.1 of NUREG-1556, Volume 7 states that the RSO must have training and specific experience with the types and quantities of licensed material to be authorized on the license. You have requested 10 millicuries (10,000 microcuries) of H-3. Mr. Smirnov's hands-on radioactive materials experience has been limited to 2.2 microcuries of C-14 per experiment. While both radionuclides are low energy beta emitters, the difference in the amount of activity is significant. The RSO is often the first responder to radioactive material spills or incidents, the RSO therefore must be prepared by training and experience to handle any such emergencies. Your proposed Authorized User, Dr. Tatianna Tolstykh, or your consultant Scott Dennerlein would appear to have the appropriate experience and training to be named RSO for the license. Mr. Smirnov could work under the direct supervision of the RSO performing delegated tasks as appropriate until he meets the training and experience per section 8.7.1 of NUREG-1556, Volume 7. You could then request an amendment at that time to

name him as RSO. If you choose to name your consultant as RSO, 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.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

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. 134787. If you have any technical questions regarding this deficiency letter, please call John Nicholson at (610) 337-5236.

M. Stock
Signum Biosciences, Inc.

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

Sincerely,

Original signed by Sattar Lodhi, Ph.D.

Kathy Dolce Modes
Health Physicist
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Enclosure:
10 CFR Parts 19, 20, and 30

cc:
Scott Dennerlein, Consultant
Vadim Smirnov, Radiation Safety Officer

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