



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

October 21, 2005

Docket No. 03036545  
Control No. 137726

License No. 29-30906-01

Maxwell Stock  
Vice President  
Signum Biosciences, Inc.  
1 Deer Park Drive  
Monmouth Junction, NJ 08852

SUBJECT: SIGNUM BIOSCIENCES, INC., REQUEST FOR ADDITIONAL INFORMATION  
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL  
NO. 137726

Dear Mr. Stock:

This is in reference to your letter dated August 3, 2005 requesting to amend Nuclear Regulatory Commission License No. 29-30906-01. In order to continue our review, we need the following additional information:

1. You have requested for David Fela to become an authorized user. In general, authorized users must demonstrate training and experience with the type and quantity of material that they propose to use. The information submitted with the amendment request stated that Mr. Fela was not experienced with radioactive materials. Please provide if there is any additional information associated with Mr. Fela's training and experience. Mr. Fela may work under the supervision of an authorized user to gain this experience.
2. Your amendment request stated that a floor plan was attached. However, no floor plan was located associated with your letter. Please submit the floor plans ensuring that it meets the guidance in section 8.9 and Appendix H of NUREG-1556, Volume 7.
3. Your amendment requested the use of laboratory animals. You did not include methods and requirements for releasing animals or disposal of animals. Please describe your procedures associated with release or disposal of animals. Guidance for these procedures are written in Appendix H of NUREG-1556, Volume 7.
4. Your "Instructions for Radioactive Material Research Utilizing Animals" states the release criteria for animal cages is less than twice "background." Please confirm that the survey methods employed demonstrates that surface contamination that is less than the criteria in Appendix Q, Table Q.2, for the radionuclides being used.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material**; then **toolkit index page**. Or you may obtain these documents by contacting the Government

M. Stock  
Signum Biosciences, Inc.

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Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 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. 137726. If you have any technical questions regarding this deficiency letter, please call Dennis Lawyer at (610) 337-5366 or me at (610) 337-5303.

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 Thomas K. Thompson***

Thomas K. Thompson  
Senior Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

cc:  
Scott Dennerlein, Radiation Safety Officer

M. Stock  
Signum Biosciences, Inc.

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**SISP Review Complete: DRL**

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DATE	10/21/2005		10/21/2005					

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