



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

July 20, 2007

Docket No. 030-37508
Control No. 140774

License No. 06-31263-01

Ronald W. Lennox
Chief Executive Officer
BioRelix, Inc
5 Science Park at Yale
New Haven, CT 06511-3572

SUBJECT: BIORELIX, INC, REQUEST FOR ADDITIONAL INFORMATION CONCERNING
APPLICATION FOR NEW LICENSE, CONTROL NO. 140774

Dear Mr. Lennox:

This is in reference to your application dated July 3, 2007, applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. Item 5 of your application requests the use of sealed sources of phosphorus-32 (P-32) and a total activity of 25 megabecquerels (MBq); however, Item 6 of your application requests the use of 25 millicuries of P-32 in any chemical or physical form for labeling and *in vitro* studies.
 - a. Confirm that you are requesting P-32 in any chemical or physical form. If you wish to be authorized for sealed sources, you must provide the manufacturer's name and model number of each sealed source you intend to possess. Typically, P-32 is used in the form of chemical compounds, which are unsealed materials and considered "any" form.
 - b. Confirm if you are requesting a total activity of 25 millicuries (mCi) or 25 MBq. The amount of 25 MBq is equivalent to 0.675 mCi.
 - c. Confirm that, in your radiation safety procedures to be developed, you will consider the following special procedures, based on of your request for more than one millicurie of P-32 and its use in labeling:
 - i. the use of low density shielding (e.g., plexiglass) in order to keep Bremsstrahlung radiation at a minimum,
 - ii. a mandatory radiation survey and wipe test for radioactive contamination after each use,
 - iii. the use of finger extremity monitors for procedures that involve one millicurie or more,

- iv. a dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the radiation protection officer be present during new procedures, and
 - v. the use of eye protection for procedures that involve handling 10 millicuries or more.
- 2. In support of your request for Izabela Puskarz and Kenneth F. Blount to use, or supervise the use of, radioactive materials, specify (1) the quantities of licensed materials they have used and (2) the duration of their experience using such quantities of materials.
- 3. As part of the application process, we plan to meet with you at your proposed facilities to discuss the application. We will contact you to schedule this site visit in the near future.

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; Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 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. 140774. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040.

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 Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Izabela Puskarz, Radiation Safety Officer

R. Lennox
BioRelix, Inc

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SUNSI Review Complete: EUllrich

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