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

October 18, 2012

Docket No. 03033449 License No. 44-30124-01MD

Richard Sucese, Pharm.D.
Facility Manager
PharmaLogic
9 Krupp Drive,
P.O. Box 786
Williston, VT 05495

SUBJECT: NRC INSPECTION REPORT NO. 03033449/2012001, PHARMALOGIC, WILLISTON, VERMONT SITE AND NOTICE OF VIOLATION

Dear Mr. Sucese:

On August 29, 2012, Todd Jackson and William Dean of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspectors, interviews with personnel, and a selective examination of representative records. Additional information provided in the telephone conversation on September 12, 2012, between you and this office and in your email dated September 26, 2012, were also examined as part of the inspection. The findings of the inspection were discussed with you at the conclusion of the inspection.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation involved the failure to dispose of licensed material only by specified procedures.

The violation is cited in the enclosed Notice of Violation (Notice), because the violation was identified by a contractor and because you had prior opportunity to identify the problem but failed to take action that would have prevented the disposal.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at

http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** 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).

Please note that the office of the Region I Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

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.

Please contact Todd Jackson at 610-337-5308 if you have any questions regarding this matter.

Sincerely,

Original signed by Elizabeth Ullrich for

Judith A. Joustra, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc: Gerald Strugala, R.Ph., Vice President, Operations
State of Vermont

Please contact Todd Jackson at 610-337-5308 if you have any questions regarding this matter.

Sincerely,

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Enclosure:
Notice of Violation

cc: Gerald Strugala, R.Ph., Vice President, Operations
State of Vermont

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OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	TJackson/TJJ		JJoustra/bu					
DATE	10/18/12		10/18/12					

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NOTICE OF VIOLATION

PharmaLogic
Williston, VT

Docket No. 03033449
License No. 44-30124-01MD

During an NRC inspection conducted on August 29 and September 26, 2012, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 20.2001 (a) requires that a licensee shall dispose of licensed material only by specified procedures. Condition 18 of License Number 44-30124-01MD authorizes the licensee to dispose of waste which has decayed in storage without regard to its radioactivity provided the specified conditions are satisfied, including item (A) which requires the licensee monitor byproduct material at the surface before disposal and determine that its radioactivity cannot be distinguished from background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding, and (C) which requires records be maintained of the survey for three years which include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
>
> Contrary to the above the licensee disposed of licensed material by transfer to a recipient not authorized to receive it, a method not authorized by 10 CFR 20.2001. Additionally, the licensee failed to decay the licensed material in storage, did not determine that radioactivity in the barrels could not be distinguished from background, and did not record the name of the individual who performed the disposal.
>
> Specifically, on March 22, 2012, the licensee transferred three barrels containing licensed materials to its waste disposal contractor, which does not have a license to possess radioactive material and is therefore not authorized to receive radioactive material. The licensee performed an inadequate radiation survey of the barrels which did not identify that the barrels contained radioactive material, and the person who recorded the radiation survey results did not record their name.
>
> This is a Severity Level IV violation (Enforcement Policy Section 6.7).

Pursuant to the provisions of 10 CFR 2.201, PharmaLogic is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be

issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 18 day of October 2012