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

October 5, 2006

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

Thomas DeFranco, R.Ph.
Manager
PharmaLogic Ltd
9 Krupp Drive
Williston, VT 05495

SUBJECT: INSPECTION 03033449/2006001, PHARMALOGIC LTD, WILLISTON, VERMONT SITE AND NOTICE OF VIOLATION

Dear Mr. DeFranco:

On September 17, 2006, Steve Hammann of this office conducted a safety inspection at the above address of activities authorized by your 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 inspector, interviews with personnel, and a selected examination of representative records. Additional information provided in the telephone conversation on October 5, 2006, between Stephen Sopchak, R.Ph. of your organization and this office, was also examined as part of the inspection. The findings of the inspection were discussed with Mr. Sopchak at the conclusion of the inspection and during the telephone conversation on October 5, 2006.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

The item described in the Notice of Violation enclosed with this letter was identified during a previous inspection of your licensed activities and documented in a Notice of Violation enclosed with our letter dated October 8, 2005. From this inspection, it appears that your corrective actions were not effective since this item has recurred. Recurrent and uncorrected violations are given additional weight in the consideration and selection of appropriate enforcement action. Therefore, in your response to this letter, you should give particular attention to those actions taken or planned to ensure that identified items of noncompliance will be completely corrected and will not recur.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Toolkit Index Page.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement,** then **Enforcement Policy.** Or you may 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).

Your cooperation with us is appreciated.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Stephen Sopchak, R.Ph., Radiation Safety Officer
State of Vermont

Distribution:
D. J. Holody, RI

DOCUMENT NAME: E:\Filenet\ML062790092.wpd

SUNSI Review Complete: SHammann
After declaring this document "An Official Agency Record" it **will** be released to the Public.

To receive a copy of this document, indicate in the box: "**C**" = Copy w/o attach/encl "**E**" = Copy w/ attach/encl "**N**" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Shammann/STH		Jdwyer/JPD					
DATE	10/05/06		10/05/06					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

PharmaLogic Ltd
Williston, VT

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

During an NRC inspection conducted on September 17, 2006, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR Part 20.1101(c) requires that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.
>
> Contrary to the above, no annual program review was performed since prior to the inspection conducted in July 2003.
>
> This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, PharmaLogic Ltd 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.

Dated This _5_ day of _October_ 2006