



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

May 27, 2018

Ruth M. Wetzel, R.Ph.
Radiation Safety Officer
Pharmalogic MT, Inc.
1 South Ocean Boulevard, Suite 206
Boca Raton, Florida 33432

SUBJECT: NRC INSPECTION 030-38401/2018-001 AND NOTICE OF VIOLATION

Dear Ms. Wetzel:

This letter refers to the unannounced inspection conducted on March 12, 2018, at your facility in Missoula, Montana. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel. The preliminary inspection findings were discussed with you at the conclusion of the onsite portion of the inspection on March 12, 2018. A final telephonic exit briefing was conducted with you on May 17, 2018.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy, which can be found at the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited and described in the enclosed Notice of Violation (Notice). The violations involved the licensee's failure to conduct its program in accordance with statements, representations, and procedures contained in the license application, and the failure to demonstrate compliance with NRC radioactive effluent limits.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice on the NRC website at: <http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf>. Information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be (was) achieved should be addressed. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction. If personal privacy

or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by Title 10 of the *Code of Federal Regulations* (CFR) 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Should you have any questions regarding this letter or the enclosed Notice, please contact Jason vonEhr at 817-200-1186, or the undersigned at 817-200-1182.

Sincerely,

/RA/

Michael C. Hay, Chief
Materials Licensing and Inspection Branch
Division of Nuclear Materials Safety

Docket: 030-38401
License: 09-29398-01MD

Enclosure:
Notice of Violation

cc:
B. Watson, Administrator
Radiation Control Program Director
State of Montana

C. Becker, Chief, Florida Bureau of
Radiation Control, State of Florida

NRC INSPECTION REPORT 030-38401/2018-001 - DATED MAY 27, 2018

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ADAMS ACCESSION NUMBER: **ML18150A400**

SUNSI Review: ADAMS: Non-Publicly Available Non-Sensitive Keyword:
By: JEV Yes No Publicly Available Sensitive

OFFICE	HP: MLIB	SHP: MLIB	C: MLIB			
NAME	JEvonEhr	JFKatanic	MCHay			
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DATE	5/21/18	5/17/18	5/27/18			

OFFICAL RECORD COPY

NOTICE OF VIOLATION

Pharmalogic MT, Inc.
Missoula, MT

Docket No. 030-38401
License No. 09-29398-01MD

During an NRC inspection conducted on March 12, 2018, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A) License Condition 21 of NRC License 09-29398-01MD, Amendment 13, dated May 26, 2017, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, contained in the license application dated July 1, 2010.

The license application dated July 1, 2010, Item 9, "Facilities and Equipment," Section 9.2 states, in part, that the air intakes are a minimum of 55 feet from the exhaust stack. Attachment 9.3 provides a drawing of the "Pharmalogic Iodine Fume Hood and Glove Box," which shows the exhaust from the radioiodine glove box joining the exhaust from the radioiodine fume hood, and the placement of the total exhaust air sampling probe above where the two exhausts joined.

Contrary to the above, from January 5, 2011, to March 12, 2018, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, contained in the license application dated July 1, 2010. Specifically, from January 5, 2011 through March 12, 2018, the licensee failed to ensure that its air intakes were a minimum of 55 feet from the exhaust stack, and joined the exhaust from the radioiodine glove box to the exhaust from the radioiodine fume hood in a manner that failed to have the placement of the total exhaust air sampling probe above where the two exhausts joined.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3.d)

- B) 10 CFR 20.1302(b)(2) requires, in part, that a licensee shall show compliance with the annual dose limit in 10 CFR 20.1301. A licensee can demonstrate compliance by demonstrating that the annual average concentrations of radioactive material released in gaseous effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix B to 10 CFR Part 20; and that if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.002 rem in an hour and 0.05 rem in a year.

Contrary to the above, from January 5, 2011, to March 12, 2018, the licensee failed to show compliance with the annual dose limit in 10 CFR 20.1301. Specifically, from January 5, 2011, to March 12, 2018, the licensee failed to demonstrate that the annual average concentrations of radioactive material released in gaseous effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix B to Part 20. The licensee failed to construct its gaseous effluent monitoring system in a manner that could be used to determine the total gaseous effluent at the boundary of the unrestricted area and therefore was unable to demonstrate compliance with 10 CFR 20.1301.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3.d)

Enclosure

Pursuant to the provisions of 10 CFR 2.201, Pharmalogic MT, Inc., is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region IV, 1600 E. Lamar Blvd., Arlington, Texas 76011, 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: (1) the reason for the violations, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; 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 requiring information 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, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

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

Dated this 27th, May 2018