



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

July 15, 2021

Mr. Gerard A. Strugala, R.Ph., Vice President
Pharmalogic MT, Inc.
1 South Ocean Boulevard, Suite 206
Boca Raton, Florida 33432

SUBJECT: RESPONSE TO NRC INSPECTION REPORT 030-38401/2021-001 AND
NOTICE OF VIOLATION

Dear Mr. Strugala:

On May 4, 2021, the U.S. Nuclear Regulatory Commission (NRC) cited Pharmalogic MT, Inc., as described in NRC Inspection Report 030-38401/2021-001 and Notice of Violation (Notice), found at the NRC's Agencywide Documents Access and Management System (ADAMS), Accession Number [ML21123A314](#). The Notice required you to reply in writing within 30 days, you responded by letters dated May 30, and June 14, 2021. A copy of your response is available in ADAMS (Accession Numbers [ML21154A302](#) and [ML21166A361](#), respectively).

After reviewing the information provided in your reply to the Notice, we have concluded that your completed and proposed actions appear to adequately address the regulatory noncompliance described in the Notice. We will review your implementation of these corrective actions during a future inspection to determine whether full compliance has been restored and whether compliance will be maintained.

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

Sincerely,

Lizette Roldan-Otero, Ph.D., Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

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

SUBJECT: RESPONSE TO NRC INSPECTION REPORT 030-38401/2021-001 AND NOTICE OF VIOLATION DATED JULY 15, 2021

DISTRIBUTION:

M.Muessle, DNMS

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R4DNMS_MIB

ADAMS ACCESSION NUMBER: **ML21196A460**

SUNSI Review: ADAMS: Non-Publicly Available Non-Sensitive Keyword:
By: JCD Yes No Publicly Available Sensitive SUNSI review complete

OFFICE	HP:MIB	C:MIB	
NAME	JDykert	LRoldan-Otero	
SIGNATURE	<i>/RA/</i>	<i>/RA/</i>	
DATE	06-15-2021	07/15/2021	

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