



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 22, 2017

Ms. Jeanne Fiore
Vice President of Regulatory Affairs and Compliance
Pharmalucence, Inc.
29 Dunham Road
Billerica, MA 01821

SUBJECT: PART 71 QUALITY ASSURANCE PROGRAM APPROVAL BIENNIAL CHANGE
REPORT

Dear Ms. Fiore:

In August of 2015, the U.S. Nuclear Regulatory Commission (NRC) issued a letter (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15245A269) describing changes made to Title 10 of the *Code of Federal Regulations* (10 CFR), Part 71 regulations. Among the changes described was a new regulation, 10 CFR 71.106, that requires changes to your Part 71 quality assurance program that do not reduce commitments be submitted to the NRC every 24-months. The reporting period started on the date your revised Form 311 was approved, which was in August of 2015.

As of the date of this letter, the NRC has not received a biennial change report as required by 10 CFR 71.106. Please submit the required report by January 31, 2018, and in accordance with the requirements in 10 CFR 71.1(a). Additional action could be taken, as necessary, during a future inspection of your program. Please note that if you did not make any changes to your quality assurance program in the preceding 24-month period, you are required to report that no changes were made.

If you wish to amend your quality assurance program approval and have determined it reduces commitments, or terminate your approval, please request it in writing.

If you have any questions, please contact me at 301-415-7399 or Jeremy Tapp at 301-415-8047.

Sincerely,

/RA Jon Woodfield Acting for/

Patricia Silva, Chief
Inspections and Operations Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No.: 71-0642

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REPORT, DOCUMENT DATE: DECEMBER 22, 2017

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