



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

August 28, 2015

Radiation Safety Officer
Pharmalucence, Inc.
10 DeAngelo Drive
Bedford, MA 01730

SUBJECT: REVISED QUALITY ASSURANCE PROGRAM APPROVAL FORM FOR
RADIOACTIVE MATERIAL PACKAGES NO. 0642, REVISION 9

Dear Sir or Madam:

On June 12, 2015, the U.S. Nuclear Regulatory Commission (NRC) issued a final rulemaking to amend 10 CFR Part 71 regulations. The effective date of this rulemaking was July 13, 2015. Among the changes made was an update to the administrative procedures for the quality assurance program requirements described in 10 CFR Part 71, Subpart H. Specifically, 10 CFR 71.38 has been amended to remove the requirements for renewal of Quality Assurance Program Approvals, and 10 CFR 71.106 was added to establish requirements that will apply to changes to quality assurance programs.

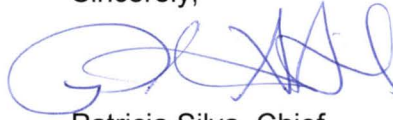
Previously, all changes made to Quality Assurance Program Approvals had to be prior reviewed and approved by the NRC before they could be implemented. The new regulations in 10 CFR 71.106 allow changes to quality assurance programs that do not reduce commitments, such as those that involve administrative improvements and clarifications and editorial changes, to be made and implemented without prior NRC approval. Quality Assurance Program Approval holders are required to receive NRC approval before implementing changes to their quality assurance program that will reduce their commitments to the NRC.

Since there is no longer an expiration date for your Quality Assurance Program Approval, the NRC has revised Form 311 to reflect this change. The enclosure to this letter contains your Quality Assurance Program Approval on the revised Form 311. In addition, 10 CFR 71.106 requires that changes to your quality assurance program that do not reduce commitments must be submitted to the NRC every 24-months, with the reporting period starting on the date your revised Form 311 was approved. 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 this Approval, please request it in writing.

Further background information regarding these changes is contained in the Federal Register Notice associated with this rulemaking, which can be found by using the following link:
<http://www.gpo.gov/fdsys/pkg/FR-2015-06-12/pdf/2015-14212.pdf>

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

Sincerely,



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

Docket No.: 71-0642

Enclosure: QA Program Approval No. 71-0642, Rev. No. 9

QUALITY ASSURANCE PROGRAM APPROVAL
FOR RADIOACTIVE MATERIAL PACKAGES

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Title 10, Code of Federal Regulations, Chapter 1, Part 71, and in reliance on statements and representations heretofore made in Item 4 by the organization named in Item 2, the Quality Assurance Program identified in Item 4 is hereby approved. This approval is issued to satisfy the requirements of Section 71.101 of 10 CFR Part 71. This approval is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

2. NAME

Pharmalucence, Inc.

STREET ADDRESS

10 DeAngelo Drive

CITY

Bedford

STATE

MA

ZIP CODE

01730

3. DOCKET NUMBER

71-0642

4. QUALITY ASSURANCE PROGRAM APPLICATION DATE(S)

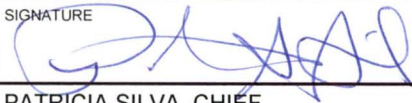
April 29, 2005 and June 18, 2008

5. CONDITIONS

1. Activities authorized by this approval: procurement, maintenance, repair, and use are to be executed with regard to transportation packagings. All other activities (i.e., design, fabrication, assembly, testing, and modification) shall be satisfied by obtaining certifications from packaging suppliers that these activities were conducted in accordance with an NRC-approved Quality Assurance Program. It shall remain the responsibility of the Quality Assurance Program holder that all transportation activities meet the requirements of 10 CFR 71.101.
2. Records shall be maintained in accordance with the provisions of 10 CFR Part 71. Specifically:
 - a. Records of each shipment of licensed material shall be maintained for 3 years after that shipment [10 CFR 71.91(a)].
 - b. Records providing evidence of packaging quality shall be maintained for 3 years after the life of the packaging [10 CFR 71.91(d)].
 - c. Records describing activities affecting packaging quality shall be maintained for 3 years after this Quality Assurance Program Approval is terminated [10 CFR 71.135].
3. Planned and periodic audits of all aspects of the Quality Assurance Program shall be conducted in accordance with written procedures or checklists, by appropriately trained personnel not having direct responsibility in the areas being audited, in accordance with 10 CFR 71.137.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

SIGNATURE



DATE

8/28/15

PATRICIA SILVA, CHIEF
INSPECTIONS AND OPERATIONS BRANCH
DIVISION OF SPENT FUEL MANAGEMENT
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

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Sincerely,

/RA/

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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OFC:	DSFM	N	DSFM		DSFM	
NAME:	JTapp		MDeBose		PSilva	
DATE:	8/6/15		8/13/15		8/28/15	

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