

September 11, 2008

Mr. Michael M. Thomson
Radiation Safety Officer
Pharmalucence, Inc.
10 DeAngelo Drive
Bedford, MA 01730

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

Dear Mr. Thomson:

Enclosed is the Quality Assurance (QA) Program Approval for Radioactive Material Packages No. 0642, Revision No. 9, for your name change from CIS-US, Inc., to Pharmalucence, Inc. This Approval satisfies the requirements of 10 CFR 71.17(b) and 71.101(f) for a QA Program approved by the U.S. Nuclear Regulatory Commission (NRC).

This Approval will remain in effect until the expiration date, indicated in Block No. 3. Termination of your materials license does not cause this Approval to be automatically terminated. If you wish to renew, amend, or terminate this Approval, please request it in writing.

This letter also serves as a reminder that if you are using or planning to use an NRC-approved packaging, you must be registered for use of that packaging with NRC. Registration for use of NRC-approved packagings should be made pursuant to 10 CFR 71.17(c)(3).

If you have any questions, please contact me at 301-492-3299 or Frank Gee at 301-492-3329.

Sincerely,

/RA/

David W. Pstrak, Chief
Rules, Inspections, and Operations Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

Docket No.: 71-0642

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

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DATE:	9/9/08		9/9/08		9/11/08	

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QUALITY ASSURANCE PROGRAM APPROVAL
FOR RADIOACTIVE MATERIAL PACKAGES

1. APPROVAL NUMBER
0642
REVISION NUMBER
9

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 5 by the organization named in Item 2, the Quality Assurance Program identified in Item 5 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.		3. EXPIRATION DATE October 31, 2018
STREET ADDRESS 10 DeAngelo Drive		4. DOCKET NUMBER 71-0642
CITY Bedford	STATE ZIP CODE MA 01730	

5. QUALITY ASSURANCE PROGRAM APPLICATION DATE(S)
April 29, 2005; and June 18, 2008

6. CONDITIONS

- 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.
- Records shall be maintained in accordance with the provisions of 10 CFR Part 71. Specifically:
 - Records of each shipment of licensed material shall be maintained for 3 years after that shipment [10 CFR 71.91(a)].
 - Records providing evidence of packaging quality shall be maintained for 3 years after the life of the packaging [10 CFR 71.91(d)].
 - Records describing activities affecting packaging quality shall be maintained for 3 years after this Quality Assurance Program Approval is terminated [10 CFR 71.135].
- 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 /RA/	DATE 9/11/2008
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DAVID W. PSTRAK, CHIEF
RULES, INSPECTIONS, AND OPERATIONS BRANCH
DIVISION OF SPENT FUEL STORAGE AND TRANSPORTATION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS