DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17858/S-040

APPROVAL LETTER

Pharmalucence, Inc. c/o Sun Pharma Company
Attention: Anila Mico, Director
Regulatory Affairs
29 Dunham Road
Billerica, MA 01821

Dear Ms. Mico:

Please refer to your Supplemental New Drug Application (sNDA) dated October 9, 2014, received October 9, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection.

We acknowledge receipt of your amendment dated January 16, 2015, February 4, 2015, June 30, 2015, November 6, 2015 and February 23, 2016, which constituted a complete response to our February 02, 2016, action letter.

This "Prior Approval" supplemental new drug application provides for:

1. Addition of Pharmalucence site located at 29 Dunham Road, Billerica MA 01821 (FEI# 3009395771) as a manufacturing site for Sulfur Colloid finished product.
2. Qualification of a new pre-sterilized 0.22 µm Millipak 200 filter to be used to sterile filter the bulk solution in the final formulation for the Sulfur Colloid Multi-dose Reaction Vial (freeze-dried injectable).
3. Use of the bulk Water for Injection (WFI), USP generated in-house WFI System located at Pharmalucence, Inc., 29 Dunham Road, Billerica MA 01821 site, as an excipient in Sulfur Colloid product formulation.
4. Retention of in-process chemistry testing for Sulfur Colloid Solution A Vial.

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Yvonne Knight, Regulatory Project Manager, at (301) 796-2133.

Sincerely,

Ramesh Raghavachari -S

Digitally signed by Ramesh Raghavachari -S
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