



ANDA 078242/S-001, S-002

Pharmalucence, Inc  
Attn: Nancy O'Neil  
10 DeAngelo Drive  
Bedford, MA 01730

Dear Madam:

This is in reference to your supplemental new drug applications dated November 6, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Kit for the Preparation of Technetium Tc-99m Mebrofenin.

This is a corrected letter being sent at your request in which the supplements were incorrectly referenced as being submitted as "Supplements-Changes Being Effectuated in 30 Days." Please note that this letter replaces the original, but the date of final approval remains August 12, 2010.

These supplemental applications, submitted as "Prior Approval Supplements," provide for the following changes:

S-001: Labeling revisions

S-002: Modification of the specifications and stability protocol to conform to those of the Reference Listed Drug (Choletec).

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

*{See appended electronic signature page}*

Paul Schwartz, Ph.D.  
Acting Director  
Division of Chemistry I  
Office of Generic Drugs  
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
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ANDA-78242	SUPPL-2	PHARMALUCENCE INC	TECHNETIUM TC -99M MEBROFENIN
ANDA-78242	SUPPL-1	PHARMALUCENCE INC	TECHNETIUM TC -99M MEBROFENIN

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/s/

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ROBERT L ISER  
08/12/2010  
Acting Director