



NDA 19-785/S-018

Lantheus Medical Imaging
Attention: Nancy Blair
Manager, Regulatory Affairs
331 Treble Cove Road
North Billerica, MA 01862

Dear Ms. Blair:

Please refer to your supplemental new drug application dated October 29, 2007, received October 30, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CARDIOLITE® Kit for the Preparation of Technetium Tc99m Sestamibi for Injection.

We acknowledge receipt of your submissions dated December 13 and 17, 2007 and April 28, 2008.

This supplemental new drug application provides for pediatric study reports submitted in response to the Agency's Written Request, dated June 27, 2007 to qualify this product for pediatric exclusivity.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, (package insert submitted April 28, 2008).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-785, S-018.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that the "long term follow-up" continues for your clinical study entitled, "A phase 3, open label, non-randomized, international, multicenter study to evaluate the efficacy and safety of Cardiolite Myocardial Perfusion imaging in pediatric subjects with Kawasaki Disease (Study 301)." You have fulfilled the pediatric study requirement for this application and we acknowledge the "on-going" status

of the post-marketing commitment described in our letter of December 21, 1990. We reiterate the commitment described in our December 21, 1990 approval letter:

1. Study #1: To study the safety and effectiveness of Cardiolite for pediatric use.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **“Postmarketing Study Commitment Protocol”**, **“Postmarketing Study Commitment Final Report”**, or **“Postmarketing Study Commitment Correspondence.”**

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Renee Tyson, Project Manager, at (301) 796-2050.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Acting Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration

Enclosure