

## Division Director's Review Memorandum

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**NDA:** 19-785  
**Product:** Cardiolite (Kit for the Preparation of Technetium Tc99m Sestamibit for Injection)  
**Sponsor:** Lantheus Medical Imaging  
**Today's date:** April 29, 2008  
**Reviewer:** Dwaine Rieves, MD/Director, Division of Medical Imaging and Hematology Products

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### 1. Overview:

This supplement was submitted to provide pediatric use information to the Cardiolite label and also to address a "Written Request" for pediatric studies. Specifically, in the original approval letter for Cardiolite (December 21, 1990), the sponsor committed, "To study the safety and effectiveness of Cardiolite for pediatric use." Over the next several years, this commitment evolved into a "Written request" letter that went through certain revisions to clarify that one of the studies (Study 301) would have an "interim" report submitted to address the "Written Request." In totality, the "Written Request" referred to three clinical studies:

Study 201: a study focused upon radiation dosimetry and pharmacokinetics

Study 301: a prospective study of the diagnostic utility of Cardiolite in pediatric subjects with Kawasaki Disease (that involves follow-up over a 10 year period)

Study 302: a retrospective case history review of patients with Kawasaki Disease who had undergone Cardiolite imaging and also coronary arteriography

### 2. Findings:

As described in detail by the sponsor and FDA review team, the supplied study results addressed the expectations of the "Written Request." However, the patients enrolled in the studies had very few abnormalities detected on arteriograms (the "truth standard") such that the performance characteristics of Cardiolite could not be fully evaluated; although the available data suggested that Cardiolite provided no diagnostic efficacy in the patients. Perhaps most notable was the finding that, on a weight-adjusted basis, the dosimetry for the pediatric patients largely paralleled that for adults (although the adult dosimetry data are expressed in non-weight adjusted terms in the label).

### 3. Conclusions:

The Cardiolite label has been revised to describe the findings from the studies and to exemplify the lack of demonstrated efficacy. The sponsor was determined to have satisfied the terms of the "Written Request" and we understand that pediatric exclusivity will be granted.

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MEDICAL OFFICER