



NDA 18-150/SE 019

Mallinckrodt, Inc.
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Dear Dr. Brodack:

Please refer to your supplemental new drug application (NDA) dated September 29, 2003, received September 30, 2003, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Thallous Chloride T1-201.

We acknowledge receipt of your submissions dated September 29, and December 19, 2003, March 2, and 10, June 11, and July 8, 2004.

This supplemental new drug application proposes for the use of Thallous Chloride T1-201 as a myocardial perfusion imaging agent, in combination with the approved pharmacologic stress agents, for a pharmacologic stress indication.

We completed our review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter for the following expanded indication:

"Thallous Chloride T1-201 is also indicated for scintigraphic imaging of the myocardium to identify changes in perfusion induced by pharmacologic stress in patients with known or suspected coronary artery disease and who cannot exercise adequately."

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 18-150/SE1 019.**" 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 are deferring submission of your pediatric studies for ages less than 18 years until 5 years after the approval of any pharmacologic stress agents in pediatric patients in the United States.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for using Thallous chloride Tl 201 for scintigraphic imaging of the myocardium to identify changes in perfusion induced by pharmacologic stress in pediatric patients less than 18 years of age.

Final Report Submission: We are deferring submission of your pediatric studies until 5 years after the approval of any pharmacologic stress agents in pediatric patients in the United States.

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated “**Required Pediatric Study Commitments**”.

If you have any questions, call Diane C. Smith, Regulatory Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

George Q. Mills, M.D., M.B.A.

Director

Division of Medical Imaging and
Radiopharmaceutical Drug Products

Office of Drug Evaluation III

Center for Drug Evaluation and Research

Enclosure Labeling

ATTACHMENT
(Agreed Draft Labeling)

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Sally Loewke
7/23/04 03:45:02 PM
Signing for G. Mills