



DEPARTMENT OF HEALTH & HUMAN SERVICES

---

Food and Drug Administration  
Rockville, MD 20857

ANDA 78-098

Mallinckrodt, Inc.  
Attention: James W. Brodack, Ph.D.  
Director, Regulatory Affairs  
675 McDonnell Blvd.  
Hazelwood, MO 63042

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 31, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Kit for the Preparation of Technetium Tc 99m Sestamibi Injection.

Reference is also made to the tentative approval letter issued by this office on February 26, 2008, and to your amendments dated May 12, June 23, July 3, and September 9, 2008.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved effective on the date of this letter. The Division of Bioequivalence has determined your Kit for the Preparation of Technetium Tc 99m Sestamibi Injection to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Cardiolite Injection (Kit for the Preparation of Technetium Tc 99m Sestamibi Injection), of Bristol Myers Squibb Pharma Company.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Amundson Road  
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "**Miscellaneous Correspondence - SPL for Approved ANDA 78-098**".

Sincerely yours,

*{See appended electronic signature page}*

Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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

/s/

-----  
Gary Buehler  
9/22/2008 12:20:37 PM