



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-084/S-016

Mallinckrodt Inc.
Attention: Janice Karibian
Regulatory Affairs Associate
675 McDonnell Blvd, 30-1
Hazelwood, MO 63042

Dear Ms. Karibian:

Please refer to your supplemental new drug application dated March 7, 2008, received March 10, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Phosphocol[®] P 32 (Chromic Phosphate P 32 Suspension).

We acknowledge receipt of your submission dated August 13, 2008.

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert to add a new warning about the risk of malignancy and revise the **ADVERSE REACTIONS** section of the package insert to include the risk for radiation injury. In addition, the Phosphocol P32 dosimetry and physical characteristics sections are revised to reflect more current data.

We completed our review of this supplemental new drug application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed labeling (text for the package insert, and/or final printed labeling (FPL) submitted on August 13, 2008).

When you issue the 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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert

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

/s/

Rafel Rieves

8/29/2008 10:26:07 AM