



NDA 17-084/S-017

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 November 21, 2008, received November 24, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Phosphocol<sup>®</sup> P 32 (Chromic Phosphate P 32 Suspension).

This "Changes Being Effected" supplemental new drug application provides for the addition of an outside container warning label. The purpose of the label is to provide additional clarification to ensure proper administration of the drug product.

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, and immediate container and carton labels).

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 17-084/S-017, SLR.**" Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Medical Imaging and Hematology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

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

Please submit one market package of the drug product when it is available.

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 Frank Lutterodt, 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: 1. Sticker Label  
2. Package Insert

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

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Rafel Rieves

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