



NDA 18-671/S-016

CARDINAL HEALTH

Attention: William Northam
Director of Manufacturing Quality
16401 East 33rd Drive
Suite 60
Aurora, CO 80011

Dear Mr. Northam:

Please refer to your supplemental new drug application dated December 13, 2007 received December 18, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sodium Iodide I 123 Diagnostic Capsules (100 μ Ci, 200 μ Ci, and 400 μ Ci).

This "Changes Being Effected" supplemental new drug application provides for a labeling change to modify the Description Section of the package insert with the addition of the following statement regarding the stabilizer: "Each capsule contains 0.3 μ g - 3 μ g Sodium Thiosulfate as a stabilizer."

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 (package insert submitted December 13, 2007).

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 18-671/S-016.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Renee Tyson, Regulatory Project Manager, at (301) 796-1476.

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

**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

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