

October 28, 2008

CAL-3-08-001

Mitzi Pennington, Site Director
Mallinckrodt, Inc.
2703 Wagner Place
Maryland Heights, MO 63043

SUBJECT: LETTERS FROM MALLINCKRODT, INC. TO THE NRC DATED
AUGUST 18, 2008, AND AUGUST 29, 2008 AND NEW INFORMATION
RECEIVED BY THE NRC

Dear Ms. Pennington:

This refers to Mallinckrodt, Inc.'s letters dated August 18, 2008, and August 29, 2008, providing clarification and updates to information that was submitted to the NRC by letters dated January 30, 2008, and March 28, 2008, regarding Items 1 and 2 of the NRC's Confirmatory Action Letter (CAL) dated February 1, 2008. This also refers to applicable new information received by the NRC via teleconference on October 2, 2008.

We have reviewed the information contained in the August 18, 2008 letter, and we have no questions at this time. The August 29, 2008 letter included updated information regarding your actions to reduce the number of molybdenum-99 breakthrough events associated with Mallinckrodt technetium-99m generators. We have no questions regarding the information contained in the letter.

Based on a teleconference between Jim Schuh of your staff and Bob Gattone of my staff on October 2, 2008, it is our understanding that your projection for completing Items 1 and 2 of the CAL (items) was extended from the fall of 2008 to the end of 2008. Therefore, in accordance with the CAL, please advise us in writing, within 30 days of the date of this letter, of your modified schedule to complete the items. Provide the details of the events and circumstances, including the timeline, and how the events and circumstances impacted your ability to complete the items timely. Also, provide a detailed description of the status of your completion of the items that includes: (1) the actions you have taken and the results achieved to date, including a timeline; (2) what potential root cause(s) of the molybdenum-99 breakthrough problem you have ruled out (including the bases for doing so); and (3) the potential root cause(s) you are still investigating. In addition, provide a detailed schedule for actions planned to complete the items, including milestone dates that you have high confidence in achieving.

M. Pennington

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I would also like to take this opportunity to address a statement that was made in the August 18 letter. Item 13 of an attachment to that letter indicated that Mr. Gattone approved a proposed label for the top of the generators. As a matter of clarification, please note that Mr. Gattone stated that he had no questions or concerns about the label. This point of clarification was also made known to Mr. Schuh during a teleconference held on August 21, 2008.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/readingrm/adams.html>.

Sincerely,

/RA/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No. 030-00001
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cc: J. Schuh, Radiation Safety Officer
State of Missouri
Orhan Suleiman, Food and Drug Administration
Michele Perry-Williams, Food and Drug Administration

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