

Summary of April 22, 2014 Teleconference

Subject: Questions Regarding Federal Register “Notice of Intent to Withdraw from Production and Distribution of the Radioisotope Germanium-68 Used for Calibration Sources” (79 FR 19610, April 9, 2014)

Participants: Mallinckrodt Pharmaceuticals, Inc: Dan Brague, Sandy Borgschulte, Roy Brown, Bill Franco, Joe Westner, Dave Gerber
Department of Energy (DOE): Marc Garland, Jehanne Gillo, Robert Waxman
National Isotope Development Center: Wolfgang Runde

Dan Brague expressed disappointment in the DOE intent to remain in the market for germanium-68 (Ge-68) for use in germanium-68/gallium-68 (Ge-68/Ga-68) generators.

Marc Garland stated direction from the DOE General Counsel’s office: since the public comment period for the Federal Register notice is still open, we can’t discuss the decision; we can only answer questions and clarify misunderstandings.

Mallinckrodt asked about stopping sales for calibration sources on April 30, 2014.

DOE responded that sales have already stopped; we no longer have orders for Ge-68 for use in calibration sources.

Mallinckrodt asked how DOE would restrict sales of Ge-68 only to customers for use in Ge-68/Ga-68 generators.

DOE responded that an end-use statement would be included in sales contracts.

Mallinckrodt thanked DOE for providing comments received from the public in response to the Federal Register notice “Consideration of Withdrawal from Commercial Production and Distribution of the Radioisotope Germanium-68” (78 FR 15009, March 8, 2013) and requested comments received from industry.

DOE responded that ~75 public comments were received, but those comments had not been requested in the Mallinckrodt message to Marc Garland (the request was for 25 comments identified on regulations.gov). Mallinckrodt subsequently requested all comments received and DOE will send the additional ~75 comments to Mallinckrodt.

DOE also responded that comments from industry were not received in response to the 78 FR 15009 request for comment; the input from industry was solicited by DOE as part of DOE’s information gathering for the evaluation of withdrawal announced in 78 FR 15009.

Mallinckrodt asked what “qualification” of Ge-68 means.

DOE responded that Ge-68/Ga-68 generator manufacturers must qualify Ge-68 from any supplier for use on their generators.

DOE stated that we view commercialization as a success. DOE’s role in the provision of isotopes is to develop production and distribution and turn production and distribution over to private industry when private industry demonstrates the ability to meet market needs.

DOE stated that once the final decision is published in the Federal Register, further discussions can take place.