

Miller, Debra

From: Sepulveda, Lymari X
Sent: Wednesday, July 06, 2016 5:21 PM
To: Rohit Mehta
Cc: Herrera, Tomas
Subject: Request for additional information

Mr. Mehta,

While drafting the amended registration certificate we noticed that the FDA 510(K) provided with your amendment request only referenced iodine-125. Meanwhile, your amendment request indicates that either iodine-125 or palladium-103 can be used for localization. Please provide the FDA 510(k) approval for the use of palladium-103 as a localization seed. If an FDA 510(K) cannot be provided, we will proceed by adding only I-125 for use as a radioactive seed for localization.

Please submit the requested information within 30 days of the date of this e-mail. The information should be submitted in an official company letter by mail or as an attachment to an e-mail.

Thanks,

Lymari Sepulveda

Mechanical Engineer

Materials Safety Licensing Branch

Division of Material Safety, State, Tribal, and Regulatory Programs

Office of Nuclear Material Safety and Safeguards