

Note to File

Date: December 28,2004

SSD Case# 05-04 International Isotopes Inc.

Subject: Note to File

From: Tomas Herrera /RA/

I spoke with Donna-Beth Howe of the MSIB-B Medical Group, she attempted to telephone her contact with the FDA. The application from International Isotopes Inc. states that they are exempted from the premarket notification procedures in Subpart E of part 807 of 21 CFR. Another attempt will be made in the first week of January to contact the FDA to determine, if this interpretation is correct and to determine if the FDA has been contacted by the applicant regarding their application for teletherapy replacement sources.