

Note to File

Date: January 05, 2005

SSD Case# 05-04 International Isotopes Inc.

Subject: Note to File

From: Tomas Herrera **/RA/**

Dr. Donna-Beth Howe of the IMNS/MSIB-B Medical Group, spoke with Ralph Shuping of the FDA and confirmed that teletherapy sources are exempt from the premarket notification (510K form).