



November 13, 2017

Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, Maryland 20993

Submitted electronically via regulations.gov

Re: Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations; Draft Guidance for Industry; Availability; FDA-2017-D-5297

Dear Dr. Gottlieb:

The Society of Nuclear Medicine and Molecular Imaging's (SNMMI) more than 17,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy research and practice.

SNMMI welcomes the publication of the draft guidance, "Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations; Draft Guidance for Industry", to assist developers of microdose radiopharmaceutical diagnostic drugs in having a clearer understanding of the nonclinical studies that are recommended to support human clinical trials and marketing authorization. SNMMI commends the FDA on the release of this guidance and believes it will help illuminate a clear pathway to full drug development (marketing authorization) for microdose radiopharmaceutical diagnostic drugs. SNMMI believes the draft guidance has the potential to provide valuable information and guidance for technical and physical requirements that are applicable to microdose radiopharmaceutical diagnostic drugs.

SNMMI appreciates the opportunity to comment on this draft guidance. As always, SNMMI is ready to discuss any of its comments or meet with FDA on the above issues. In this regard, please contact Caitlin Kubler, Senior Manager, Regulatory Affairs, by email at ckubler@snmmi.org or by phone at 703-326-1190.

Sincerely,

A handwritten signature in black ink that reads "Bennett S. Greenspan, MD, M.S." in a cursive script.

Bennett S. Greenspan, MD, FACNM, FACR
President, SNMMI