FDA-NRC Workshop
Enhancing Development of Emerging Technologies: Radiopharmaceuticals and Radiological Devices
Wednesday, October 14, 2020
08:00 am EST to 5:00 pm EST
Virtual Workshop

Objectives
1. Develop collaborative approaches among stakeholders in development of new drug products and devices with emphasis on addressing unmet medical needs for serious and life-threatening conditions.
2. Expedite regulatory reviews and increase the overall efficiency of the development process to ensure timely access for patients to emerging therapies.

Welcome and Introductions

Session I: Overview of Regulatory Process for Marketing and Licensing of Radiopharmaceutical Products
- FDA, NRC Product Jurisdiction: Devices, Drugs and Combination Products
- Clinical Development of Radiopharmaceutical Products: Considerations for FDA Approval and NRC Licensing

Session II: Novel Radiopharmaceuticals: Standards Development, Product Quality Considerations, Supply and Demand
- Actinium-225 Accelerator Program (BNL) and Lutetium-177 Production
- Development of Physical Standards for Novel Radionuclides: Experience with Alpha-Emitters
- Product Quality Considerations: FDA perspective on diagnostic and therapeutic radiopharmaceuticals
- Special Considerations for Ge-68/Ga-68, Mo-99/Tc-99m Generators
• Product Quality Considerations: Industry experiences with radiopharmaceuticals approval and licensing. (Ge-68/Ga-68 Generators, Mo-99/Tc-99m Generators, Ga-68 Dotatate/Lu-177 Dotatate)
• Sessions I and II Panel discussion, Q&A

Session III: Safety and Efficacy Considerations for Radiopharmaceutical Products
• Pharmacology and Biodistribution of Radiopharmaceuticals
• Radiation Absorbed-dose Estimation: use is specific populations and assessment of extravasation events
• NRC perspective on extravasation events
• Role of Individualized Dosimetry to Optimize Safety and Efficacy of Radiopharmaceutical Therapies
• Role of Dosimetric Studies in Clinical Development of Radiotherapeutic Products-Industry Perspective:
• Session III Panel discussion, Q&A

Session IV: The Evolving Landscape—Radiological Devices
• Radiological Devices: Total Product Life Cycle
• Sealed Sources and Device Registry
• Gammaknife and Microspheres: NRC perspective
• Industry Experience in Regulatory Process for Radiological Devices
• Session IV Panel Discussion, Q&A

Session V: Clinical Trial Design Considerations for Radiopharmaceuticals
• Safety Assessment for Radiotherapeutics
• Efficacy Considerations for Theranostic Pairs
• Clinical Trial Considerations from an Academic Perspective
• Patients and Physician Perspectives on Advancements in Radiotherapeutics
• Session V Panel Discussion, Q&A

Closing Remarks: Summary, Next steps