August 14, 2020

Title: U.S. Food and Drug Administration (FDA) and U.S. Nuclear Regulatory Commission (NRC) Workshop
Enhancing Development of Novel Technologies: Radiopharmaceuticals and Radiological Devices

Date(s) and Time(s): October 14, 2020, 08:00 AM to 05:00 PM

The time of the meeting is local to the jurisdiction where the meeting is being held.

Location: Webinar

Category: This is a Category 3 meeting. Public participation is actively sought for this meeting to fully engage the public in a discussion of regulatory issues.

Purpose: The objectives of this FDA-NRC workshop are:
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.

Topics for Discussion:
-Overview of Regulatory Process for Marketing and Licensing of Radiopharmaceutical Devices
-Novel Radiopharmaceuticals: physical standards development, product quality considerations, supply and demand
-Safety and Efficacy Considerations for Radiopharmaceutical Products
-The Evolving Landscape—Radiological Devices
-Clinical Trial Design Considerations for Radiopharmaceuticals

Please see the FDA's Website for additional information: https://www.fda.gov/drugs/news-events-human-drugs/fda-nrc-workshop-enhancing-development-emerging-technologies-radiopharmaceuticals-and-radiological

Contact:

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Participants:

NRC	External
Office of Nuclear Material Safety and Safeguards	US Food and Drug Administration

Webinar:

URL	Meeting Number	Password
https://usnrc.webex.com/usnrc/onstage/g.php?MTID=eabeba69a55ff5fc6faf8d90db0b2e450	199 171 3631	FDA-NRC

Comments: The October 14th workshop will be conducted using Cisco WebEx. To participate in the workshop, please pre-register using the webinar link provided above.

In addition to WebEx, a live webcast of the workshop WebEx will be available at https://video.nrc.gov/

PUBLIC MEETING AGENDA

U.S. Food and Drug Administration (FDA) and U.S. Nuclear Regulatory Commission (NRC) Workshop Enhancing Development of Novel Technologies: Radiopharmaceuticals and Radiological Devices

October 14, 2020, 08:00 AM to 05:00 PM

Webinar

8:00 - 8:15 a.m. EDT - Welcome and Introductions

8:15 - 8:55 a.m. EDT - 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

8:55 - 10:20 a.m. EDT - Session II: Novel Radiopharmaceuticals: Standards Development, Product Quality Considerations, Supply and Demand

- DOE Isotope Program Production of Radioisotopes for Medical Applications
- 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)

10:20 - 10:35 a.m. EDT - BREAK

10:35 - 11:05 a.m. EDT - Sessions I and II Panel Discussion and Q&A

11:05 a.m. - 12:00 p.m. EDT - Session III: Safety and Efficacy Considerations for Radiopharmaceutical Products

- Pharmacology and Biodistribution of Radiopharmaceuticals
- Radiation Absorbed-dose Estimation: Use in 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:

12:00 - 12:45 p.m. EDT - LUNCH

12:45 - 1:15 p.m. EDT - Session III Panel Discussion and 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

5:00 p.m. EDT - Closing Remarks: Summary, Next Steps

Note: Questions may be submitted ahead of time to Lisa Dimmick, NRC Medical Team Leader, at Lisa.Dimmick@nrc.gov .

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If reasonable accommodation is needed to participate in this meeting, or if a meeting notice, transcript, or other information from this meeting is needed in another format (e.g., Braille, large print), please notify the NRC meeting contact. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

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Office	NRC/NMSS/MSST/MSEB
Name	L. Dimmick
Date	08/14/2020

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Link to meeting details: https://www.nrc.gov/pmns/mtg?do=details&Code=20201009

Commission's Policy Statement on "Enhancing Public Participation in NRC Meetings"
67 Federal Register 36920, May 28, 2002
The policy statement may be found on the NRC website
http://www.nrc.gov/reading-rm/doc-collections/commission/policy/67fr36920.html