



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

August 22, 2019

Shaemus Gleason  
Global Radiopharmaceutical Strategic  
Operations Leader  
Pharmaceuticals Division  
Bayer Healthcare Pharmaceuticals Inc.  
Oncology SBU  
Whippany, NJ 07981

SUBJECT: LICENSING OF TH-227 CHLORIDE

Dear Mr. Gleason:

Thank you for meeting with the U.S. Nuclear Regulatory Commission (NRC) staff concerning Bayer's Thorium-227 (Th-227) chloride treatment (TTC) last July. The purpose of our meeting was to obtain additional information regarding the Th-227 used to produce TTC, and the proper application of NRC requirements under the Atomic Energy Act of 1954, as amended (AEA) and NRC regulations with regard to this material, specifically, whether it constitutes "byproduct material" or "source material." We discussed targeted alpha therapy, the TTC manufacturing and administration processes, and radiation protection information for TTC.

The definition of byproduct material under AEA § 11e.1 includes "any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material." Because Th-227 is expressly a decay product of material produced in a nuclear reactor, this material falls squarely within this definition, and therefore constitutes byproduct material under the AEA and NRC regulations. Therefore, Th-227 in TTC would be licensed as byproduct material under Title 10 of the *Code of Federal Regulations (10 CFR)*, Parts 30 and 35 or equivalent NRC Agreement State provisions for animal and bench research and for medical use. We previously communicated this information verbally subsequent to Bayer's visit in July 2018. Per your request, we are providing this response in writing to facilitate licensing of TTC at your clinical trial sites.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access Management System (ADAMS). ADAMS is accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>. If you have any questions please contact myself or Said Daibes, Ph.D. at [Said.DaibesFigueroa@nrc.gov](mailto:Said.DaibesFigueroa@nrc.gov) or (301) 415-6863.

Sincerely,

*/RA/*

Christian Einberg, Branch Chief  
Medical Safety and Events Assessment Branch  
Division of Materials Safety, Security, State  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

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**ADAMS Accession No.: ML19197A327**

**\*via email**

OFFICE	MSST	MSST	MSST	OGC	
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DATE	7/17/19	8/22/19	7/17/19	8/13/19	

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