



Licensing of Radium-223 Dichloride

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Overview

- History
- Issues
- Options
- Path Forward

Previous Milestones: April 17, 2012

- Bayer provided an informational presentation to ACMUI
- ACMUI created a subcommittee to provide recommendations on licensing alpha emitters, including Ra-223, to NRC

Previous Milestones: July 9, 2012

- ACMUI provided NRC a draft subcommittee report with recommendations for
 - Licensing Ra-223 under 10 CFR 35.300
 - Requiring an appropriate radioassay system for measurement of activity prior to and after administration using a NIST-traceable standard
- ACMUI to revise report to clarify drug status

Previous Milestones: July 16, 2012

- ACMUI provided final subcommittee report with substantive changes
 - Removal of wording “requiring” a radioassay system for direct measurement of activity before/after administration
 - Removal of statement that these recommendations apply to any future alpha particle-emitting radiopharmaceuticals
 - Removal of statement that Ra-223 dichloride “significantly prolongs survival”

Issue: Measurement of Activity

- Direct measurement of activity of unsealed byproduct material used under 10 CFR 35.300 is not required before or after administration
 - [10 CFR 35.63](#) applies
 - Direct measurement is one of three options in 35.63
- If ACMUI recommends this practice as a requirement for the medical use of Ra-223 dichloride, Ra-223 dichloride will need to be regulated under 10 CFR Part 35.1000

Options: Measurement of Activity

- Revise report to:
 - Recommend the medical use of Ra-223 dichloride under 10 CFR 35.300 without a requirement for direct measurement of activity before/after administration
 - Recommend the medical use of Ra-223 dichloride under 10 CFR 35.1000 with a requirement for direct measurement of activity before/after administration
 - Recommend a rulemaking change for requiring direct measurement of activity for all unsealed byproduct material for which a written directive is required

Path Forward

- Clarify intent regarding direct measurement of activity before/after administration
- Acknowledge report changes regarding removal of statements about applicability for future alpha particle-emitting radiopharmaceuticals and prolonged survival
- Vote on final report
- Submit to NRC

Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- CFR – Code of Federal Regulations
- Ra-223 – radium 223