

TELECONFERENCE MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

July 9, 2012

MEETING SUMMARY

PURPOSE

To discuss the draft Advisory Committee on the Medical Uses of Isotopes (ACMUI) subcommittee report on licensing for radium-223 (Ra-223) dichloride.

OUTCOME

The subcommittee provided a draft report for discussion with the full committee. Subcommittee members included: Ms. Darice Bailey; Dr. Susan Langhorst; Mr. Steven Mattmuller; Dr. Christopher Palestro; Dr. Orhan Suleiman; Dr. Bruce Thomadsen; Dr. James Welsh; and Dr. Pat Zanzonico (chair). During the meeting, the committee unanimously approved the draft report with minor clarifying modifications. The U.S. Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI, as well as other stakeholders' views and opinions. The final report will be submitted to the NRC, and the staff will consider the ACMUI's recommendations in its continuing effort to make 10 Code of Federal Regulations (CFR) Part 35 more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety.

Full transcripts of the ACMUI meeting can be found on NRC's public website:

<http://www.nrc.gov/reading-rm/doc-collections/acmui/tr/>

Handouts from the ACMUI meeting can be found on NRC's public website:

<http://www.nrc.gov/reading-rm/doc-collections/acmui/meeting-slides/>

The final ACMUI report on licensing for Ra-223 dichloride will be available on NRC's public website under "Related Information": <http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html>

ATTENDEES

ACMUI

Darice G. Bailey	Member
Milton S. Guiberteau, M.D.	Member
Susan M. Langhorst, Ph.D.	Member
Leon S. Malmud, M.D.	Chairman
Steve R. Mattmuller	Member
Christopher J. Palestro, M.D.	Member
John H. Suh, M.D.	Member
Bruce R. Thomadsen Ph.D.	Vice Chairman
William A. Van Decker, M.D.	Member
Laura Weil	Member
James S. Welsh, M.D.	Member
Pat Zanzonico, Ph.D	Member

NRC

Brian McDermott	Director, Division of Materials Safety and State Agreements
Christian Einberg	Acting Deputy Director, Division of Materials Safety and State Agreements
Janine Katanic, Ph.D.	Acting Chief, Radioactive Materials Safety Branch
Michael Fuller	Designated Federal Officer and Medical Radiation Safety Team Leader
Ashley Cockerham	Alternate Designated Federal Officer and ACMUI Coordinator
Susan Chidakel	NRC staff, Office of the General Counsel
Sara Forster	NRC staff Region III
Cassandra Frazier	NRC staff Region III
Sandra Gabriel, Ph.D.	NRC staff Region I
Donna-Beth Howe, Ph.D.	NRC staff
Penny Lanzisera	NRC staff Region I
Ronald Zelac, Ph.D.	NRC staff

MEMBERS OF THE PUBLIC

Scott Bertetti - Bayer	Gary Lunger – Bayer
Dr. Colin Biggin – Algeta	Khalid Malmouk - Algeta
Jeffrey Bova - Bayer	Dr. Pierre Mapouyat – Bayer
Robert Dansereau – NY State Dept of Health	Janette Merrill – Society of Nuclear Medicine
William Davidson – University of Pennsylvania	Dr. Erik Merten – Bayer
Dr. Lothar Everz – Bayer	Michael Peters – Am. College of Radiology
Lynne Fairobent – Am. Assoc. of Physicists in Medicine	Dr. Jeffry Siegel – Nuclear Physics Enterprises
Dr. Jose Garcia-Vargas - Bayer	Michael Sheetz – University of Pittsburgh
Maria Garrigan - Bayer	Dr. Michael Tomblyn - Moffitt Cancer Center & Research Institute
Dr. Joseph Germino - Bayer	Cindy Tomlinson – Am. Soc. for Rad. Onc.
Alan Jackson - Henry Ford Hospital	Dr. Dimitris Voliotis - Bayer
John Jacobus - National Institutes of Health	Dr. Mona Wahba - Bayer
Dr. Deepika Jalota – Bayer	Gary Williams – Veterans Health Administration
Dr. Janaki Krishnamoorthy – NY State Dept of Health	Matt Williamson – Memorial Sloan-Kettering Cancer Center
Karen Langley – Univeristy of Utah	Nancy Young – Xcenda
Ralph Lieto – St. Joseph Mercy Hospital	Jessie Zhou - Bayer
Dr. Peter Luehrs – Bayer	

RECOMMENDATIONS AND ACTIONS

The subcommittee recommended licensing authorized users for Ra-223 dichloride under 10 CFR 35.390 (Category (G)(3) or (G)(4)), or 10 CFR 35.396(d)(2) and noted the same would likely apply to any future alpha particle-emitting radiopharmaceuticals. The subcommittee further recommended that an appropriate radioassay system be used to measure the Ra-223 dichloride activity prior to the administration of the radiopharmaceutical and the residual activity after the administration of the radiopharmaceutical. The committee discussed making minor changes to the report to consistently identify Ra-223 dichloride as a drug approved by the U.S. Food and Drug Administration for investigational use. The Draft ACMUI Subcommittee Report on Licensing Radium-223 Dichloride (ML12185A262) was unanimously approved and will be submitted to NRC staff for consideration.