Coalition for PET Drug Approval

Coalition for PET Drug Approval Update

Henry VanBroedklin
University of California San Francisco
Coalition Co-Chair
How was the Coalition formed?

- November 2010 a stakeholder umbrella organization was formed following an SNM Leadership meeting with Jane Axelrad

- Coalition for PET Drug Approval – founding members
  - The Academy of Molecular Imaging
  - The American Pharmacists Association, Nuclear Pharmacy Section
  - The Council on Radionuclides and Radiopharmaceuticals
  - The Medical Imaging & Technology Alliance
  - The National Association of Nuclear Pharmacies
  - The Society of Molecular Imaging
  - The Society of Nuclear Medicine
  - The Society of Radiopharmaceutical Sciences
  - United Pharmacy Partners, LLC
Current Coalition Member Groups

- American Pharmacists Association, Nuclear Pharmacy Practice Section
- American Society of Nuclear Cardiology
- Council on Radionuclides and Radiopharmaceuticals
- Medical Imaging & Technology Alliance
- National Association of Nuclear Pharmacies
- Society of Nuclear Medicine and Molecular Imaging
- Society of Radiopharmaceutical Sciences
- United Pharmacy Partners, LLC
- World Molecular Imaging Society
Why was the Coalition formed?

“The purpose of the coalition is to help our community understand requirements related to the implementation of 21 CFR part 212 and the submission process for PET NDAs or ANDAs, and to make a positive impact on the overall implementation process through interaction with the FDA.”

• Initially planned to sunset once the ANDA/ NDA submission process was complete in December 2011.
Coalition Accomplishments

- Regular conference calls to disseminate information and gather questions, concerns and issues
- Established website coalitionforpetdrugapproval.org
- Regular interaction with Jane Axelrad at FDA
- In November 2010 the Coalition requested a stakeholder meeting with the FDA
- Coalition organized questions from member organizations at the FDA meeting in March 2011
- Actively participated in stakeholder FDA meeting March 2011
Coalition Accomplishments

- Organized sessions at SNM and WMIS to assist manufacturer compliance – including sponsorship of current session
- Successfully petitioned for ANDA/NDA submission extension due to the Rb generator recall.
- Followed GDUFA legislation– generic drug fees
- Inspection Survey with SNMMI assistance
- Brenda Uratani tribute article
Future of the Coalition

• Formation of an independent trade association of PET drug manufacturers
  – Members would be the manufacturers not the professional societies
  – Advocate for stakeholders to FDA, Congress
  – Workshops and potentially expanded website
  – Rename the Coalition to reflect new roles

• Coalition face to face meeting
  – This afternoon 3:30 to 5 PM
  – Room 264
Acknowledgements

- SNMMI for hosting the Coalition since 2010
  - Sue Bunning
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