Coalition of PET Drug Manufacturers: A New Trade Association?

Henry VanBrocklin, Sally Schwarz
Coalition Co-Chairs

Website: coalitionforpetdrugs.org/
Coalition for PET Drug Approval

• November 2010 a stakeholder umbrella organization was formed following an SNMMI leadership meeting with Jane Axelrad (FDA Deputy Commissioner)

• Coalition goals 2010:
  • Assist PET drug manufacturers in navigating the NDA/ANDA process
  • Provider of education and regulatory information for PET drug manufacturers
Coalition History

• “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”

• First FDA workshop March 2011
  • Coalition met prior to workshop to discuss Part 212
  • Create questions for each of the Part 212 sections for presentation at the workshop

• SNMMI hosted and maintained website since 2011 (coalitionforpetdrugs.org)

• Initially planned to sunset once the ANDA/NDA submission process was complete, June 2012
Coalition Activities

• Since 2011 has organized and commented on numerous FDA regulations, revisions and guidance documents

• Organized and sponsored multiple CE sessions at SNMMI Annual and Mid-Winter meetings
  - FDA inspections and regulatory topics
  - USP regulatory topics
  - Radiopharmaceutical science topics

• Coalition meetings held annually at SNMMI AM
Coalition Activities

• Removal of USP monographs for non-approved PET products
  - “The Future of USP Monographs for PET Drugs” – JNM 2013
• Revision of USP general chapters including USP <823> to reflect 21 CFR Part 212
• Quality Systems Personnel Training Program
  • Member content preparation and reviewed lectures – assisted SNMMI development
  • Shared with FDA
• Feb 2020 FDA Workshop “PET Drugs: A workshop on inspections management and regulatory issues”
  • 2020 workshop proceedings paper in progress
Name Reflects Coalition Focus

2011-2014: Coalition for PET Drug Approvals

2014-2020: Coalition for PET Drugs

2021: Coalition of PET Drug Manufacturers
Our vision is to be the nationally recognized entity for educational, scientific, and regulatory information on PET drug manufacturing under 21 CFR Part 212.
CPDM Mission

The Coalition of PET Drug Manufacturers is a venue for the PET drug manufacturing community to advance scientific and regulatory principles associated with the manufacturing of PET drugs. The key elements of this mission are to:

• Provide a multi-stakeholder forum to address current topics with government agencies and other groups
• Establish scientifically sound and rational practices for PET drug manufacturing
• Provide education and training
• Enable the expansion of new PET drugs into routine manufacturing networks
• Provide high-value resources to assist PET Drug Manufacturers with GMP compliance and inspection challenges
• Align the interests of the community of PET Drug Manufacturers
Why an Independent Coalition?

• Coalition provides an interface between the FDA and the PET manufacturing community to enable the development of scientifically sound and rational regulations and practices associated with the manufacture of PET drugs.

• An independent entity will enable interface with the FDA

• This community consists of academic, government and commercial groups located at more than 150 manufacturing facilities across the US

• It is widely acknowledged that PET drugs demand specific considerations to remain a safe and cost-effective diagnostic modality

• The Coalition is the only organization dedicated to the interests of this unique drug manufacturing environment

• Primary focus is on assisting community with FDA inspections
What’s Next?

• The interests of PET drug manufacturers would be best served if the Coalition evolves into a 501(c)(6) trade association

• This will permit commercial and academic participation

• A recent survey of academic, government and commercial PET drug manufacturers (50% response) indicated strong support (>90%) for this transition and their willingness to pay dues to fund the trade association

• In negotiation with SNMMI for Coalition management

• Coalition would cover expenses of this relationship by member dues
Deliverables

• Assisting and maintaining changes to approved applications
• Congruency between NDA/ANDA filing commitments and site inspections
• Predictable acceptability and implementation of risk-management policies
• Clarity about on-site vs remote FDA inspection practices and stakeholder communication
• FDA Audit training: Resources to assist with a successful FDA audit
• Anonymous mechanism to challenge inspection findings. Peer feedback on audit findings
• Clarification of GMP, GMP education and training, as well as customizable resource tools to meet the annual training compliance requirements for staff
• Resources for filing ANDAs for non-proprietary tracers
• Routine summary and interpretation of FDA audit findings and trends
Coalition Leadership Team

Christina Arenas
Sue Bunning
Christopher Ignace
Steve Mattmuller
Sally Schwarz
Peter Scott
Henry VanBrocklin
Steve Zigler
Website: coalitionforpetdrugs.org/