1. Welcome & introduction
   Henry VanBrocklin & Steve Zigler provided:
   a. The disclaimer/caveats located here: https://www.petdrugmanufacturers.org/caveats
   b. A slide identifying the current members of the Coalition’s leadership team
   c. A reminder that the Coalition’s mission is to advance scientific and regulatory principles associated with the manufacturing of safe and effective PET drugs
   d. A brief reminder about how the Coalition works, emphasizing that Coalition members drive policy through consensus
   e. Remarks about how the Coalition will be conducting a survey to gain data on the safety of PET drugs; that this data will be used to write a white paper.

2. Brief organizational updates: finances, federal (c)(6) status, dues season, etc.
   Peter Scott reported:
   a. The Coalition is in good fiscal health and currently has $26,217 in its operations account.
   b. The IRS has determined that the Coalition is a Federal 501(c)(6), tax-exempt organization.
   c. We will start our dues renewal season in April 2023.

3. Brief FDA Workshop update
   Steve Zigler noted:
   a. The Coalition, SNMMI, MITA, and WMIS recently sent a proposed agenda to Dr. Lou Marzella for the “2nd Workshop on Inspections Management and Regulatory Considerations.”
   b. Proceedings from the first workshop can be found here:
      https://jnm.snmjournals.org/content/jnumed/early/2022/01/20/jnumed.121.263443.full.pdf
   c. Video of the sessions can be found here: https://www.fda.gov/drugs/pet-drugs-workshop-inspections-management-and-regulatory-considerations-02212020-02212020
   d. Shortly after our Open Board Meeting, the FDA indicated that they would like to hold the workshop this Fall at the FDA’s White Oak Conference Center in Silver Springs, MD (virtual option, too).

4. Working groups updates
   a. Regulatory Pathways Working Group
      Steve Mattmuller led attendees through the simple survey form. Attendees suggested that:
      i. “Contract Manufacturers” be added to the list of possible manufacturing sites
      ii. We reverse the order of the survey, starting with pathway selection first
      iii. We provide a drop-down list of drugs to choose from as well as an “Other” option
      iv. We add a footnote that states something like: “Products manufactured according to 21 CFR Part 211 should not be included in the survey.”
   b. FDA Intelligence Working Group
      Peter Scott led attendees through this survey form. Attendees suggested that:
      i. It might be helpful to learn if a responding site has also participated in CTN surveys; perhaps would could gain additional information from the CTN.
      ii. The survey could be set up to provide a shared “interpretation” of a GMP requirement or section. This way, colleagues could provide feedback from inspections, thus helping others prepare how their SOPs are written and draft responses.
      iii. One of the working group members suggested that item ii above could be best handled in the forum that is being developed.
   c. Effective Communication Working Group
      Nick Freiburger gave an update on the development of the Coalition’s forum. Testing should begin soon.

5. Next Steps
   Henry VanBrocklin stated that the Coalition will:
   a. Hold an open board meeting at the June SNMMI meeting
   b. Work with the FDA and Coalition partners/members to organize the “2nd Workshop on Inspections Management and Regulatory Considerations” (hybrid event to be held this Fall at the FDA’s White Oak Conference Center in Silver Springs, MD)
   c. Lastly, Henry requested that members keep their ears and eyes open for information from the FDA about potential revisions to 21 CFR Part 212.