Welcome

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President Elect
Society of Nuclear Medicine and Molecular Imaging

November 13, 2023

Overarching Mission: Working together we advance healthcare for patients

- Ensure safety and quality of radiopharmaceuticals
- Patient access to radiopharmaceuticals
  - Diagnoses
  - Inform patient management
  - Monitor response
  - Change management

Demographics of PET Drugs

As of October 27, 2023—

• There are 21 PET drugs currently approved by the FDA in the US (up from 12 in 2020)
• There are approximately 50 NDA/ANDA holders for PET drugs in the US
• Approved PET drugs are labeled with a variety of isotopes including F-18, Ga-68, Cu-64, Rb-82, C-11 and N-13
• Over 50 new PET drugs are in development as companion imaging agents for theranostic agents

Other demographic data for PET drugs —

• An estimated 2.495 million PET scans were performed in the US in 2022; FDG accounted for about 82% of these scans.¹
• Estimated sales of all PET drugs in the US in 2022 is $461.1M¹

¹PET Imaging Market Summary Report 2023, IMV Market Research
Questions Submitted to the FDA

The FDA offered to answer questions from the PET manufacturing/nuclear medicine community. A request for questions was sent to approximately 15,000 individuals in the PET manufacturing/nuclear medicine community in advance of the Workshop. Questions were grouped into:

- Facility Inspections and Compliance
- Product Quality and Regulatory Submissions
- Product Safety and Risk Assessment
- Management of the PET Drug Lifecycle
- Other

We want to thank the FDA for reviewing and researching the questions and look forward to discussing the answers today and tomorrow.

Welcome

Sue Bunning

Industry Managing Director, Positron Emission Tomography Medical Imaging & Technology Alliance
Welcome

Charles Metzger
Executive Director
Coalition of PET Drug Manufacturers
November 13, 2023

Acknowledgements

- FDA and other sponsors
- Non-FDA speakers are here to represent all academic and commercial PET drug manufacturers
- The content and views expressed in their presentations are the result of a consensus by the authors with input from other PET drug manufacturers and are not necessarily views of the organizations they represent
Background

- The Coalition helped organize the February 2020 workshop “PET Drugs: A workshop on inspections management and regulatory issues”
- Published proceedings of the workshop in JNM

Predominant Workshop Themes from 2020

1. Need for uniformity in FDA inspections of PET facilities
2. Need for a science-based risk profile for PET drugs
3. Improvements to training for FDA investigators and the regulated community
4. The need for continued dialog between the FDA and the PET community
2023 Survey of PET Drug Manufacturers

- Survey of academic and commercial PET drug manufacturers conducted by the Coalition in Sep 2023
- Sent to all known PET drug manufacturers in the US and responses were anonymously compiled by the Coalition
- Eighteen (18) responses were received - 68,819 batches under NDA and/or ANDA applications
- Coalition believes data sources are reliable but does not warrant the results and does not assume any liability for the accuracy or comprehensiveness of the information
- Email Charles to participate in this anonymous survey