Bi-Annual Industry Regulatory Science Working Group Meeting
Meeting Minutes
August 6, 2025
9:30 AM to 11:00 AM ET
MS Teams Meeting

9:30 AM – 9:40 AM **Introductions**

FDA	**FDA** (continued)	**Industry**
Ahmed Zidan Andrew Babiskin Bhagwant Rege Bryan Newman Cameron Smith Heather Boyce Jessie Floura Jihong Shon Lei Zhang Manar Al-Ghabeish Markham Luke Maria Monroy-Osorio Nilufer Tampal Qi Zhang Robert Lionberger Sam Raney	Sarah Ibrahim William Smith Yan Wang	**AAM** Giuseppe Randazzo Kiran Krishnan Scott Kuzner **Amneal Pharmaceuticals** Andrew Zacher **Fresenius-Kabi** Aparna Dager **Lupin Pharmaceuticals** Kalpana Vanam **Sandoz, Inc.** Jessica Greenbaum **Teva Pharmaceuticals** Aaron Josephson

9:40 AM – 10:20 AM **Brief Review of Industry Input on Fiscal Year (FY) 2026 GDUFA Research Priorities During the FY 2025 GDUFA Public Workshop Sessions**

Dr. Sam Raney provided an overview of the FY 2025 GDUFA Public Workshop, discussing the overarching structure of the workshop, faculty presentations, public comments, and panel discussions.

Dr. Raney then facilitated a discussion summarizing the input received during each session of the public workshop. Designated representatives from FDA summarized the key feedback received from workshop faculty and the public for each session of the workshop. There was generally concurrence among workshop faculty, including representative from industry and FDA, and the public about the research areas that should be prioritized for FY 2026.

The sessions for the FY 2025 GDUFA Public Workshop discussed were:

- **Session 1: Assessment Challenges with Complex Active Ingredients: Peptides & Oligonucleotides**
  Session Summary by Dr. Cameron Smith and Dr. Yan Wang

Areas of Focus: Comments during Session 1 of the GDUFA public workshop highlighted scientific challenges and research opportunities relating to complex drug substance characterization, impurity profile characterization, and immunogenicity risk assessment standardization for oligonucleotide and peptide products; specific areas of focus included development and regulatory assessment of generic peptide products manufactured using recombinant processes, development of standardized immunogenicity assays, and host cell impurity assessment.

- **Session 2: Tackling Formulation Sameness and Advancing In Vitro Characterization for Bioequivalence of Complex Generic Products**
  Session Summary by Dr. Bryan Newman and Dr. Ahmed Zidan

  Areas of Focus: Comments during Session 2 of the GDUFA public workshop highlighted scientific challenges and research opportunities relating to bioequivalence approaches for long-acting injectable products; in vitro characterization methods, in silico predictive modeling and simulation methods; and bioequivalence testing for nasal and inhalation productions, including for dissolution testing methodologies as well as study designs for pharmacokinetic bioequivalence studies with charcoal-block.

- **Session 3: Future Horizons for Assessing the Bioequivalence of Complex Products: Challenges in the Next Five Years**
  Session Summary by Dr. Bryan Newman and Dr. Ahmed Zidan

  Areas of Focus: Comments during Session 3 of the GDUFA public workshop highlighted scientific challenges and research opportunities relating to future bioequivalence approaches for transdermal delivery systems; inhalation and nasal drug delivery technologies; user interface design characterization; and the integration of artificial intelligence and machine learning approaches to support a demonstration of bioequivalence.

- **Session 4: Implementation of the M13A Guidance: Lessons Learned and Advances for Immediate Release Products**
  Session Summary by Dr. Nilufer Tampal

  Areas of Focus: Comments during Session 4 of the GDUFA public workshop highlighted scientific challenges and research opportunities relating to M13A guidance implementation for solid oral immediate release (IR) products; complex manufacturing and process technology for IR products; amorphous solid dispersions and lipid-based formulations; BCS Class I, II, and IV challenges; in vitro-in vivo correlation (IVIVC) challenges and bio-predictive media development

- **Session 5: Challenges and Opportunities for Modified Release Generic Products**
  Session Summary by Dr. Manar Al-Ghabeish and Dr. Nilufer Tampal

  Areas of Focus: Comments during Session 5 of the GDUFA public workshop highlighted scientific challenges and research opportunities relating to demonstrations of equivalence without bioequivalence in vivo studies; drug product strength-to-strength extrapolation criteria and considerations; alternatives to traditional animal models; pharmacokinetic matrices evaluation; lipid-based formulations; and 3D printing technology quality considerations.

10:20 AM – 10:45 AM Discussion of Draft FY 2026 GDUFA Research Priorities

Dr. Raney illustrated how the feedback provided to FDA during the FY 2025 GDUFA Public Workshop guided the development of the FY 2026 GDUFA Science and Research Priorities. Prior to the meeting, the draft FY 2026 Research Priorities were shared with meeting attendees. Dr. Raney noted that some FY 2025 GDUFA Research Priorities, which were drafted a few years ago, were largely unchanged for FY 2026 because the feedback to FDA indicated that those research areas continued to be a priority.

The proposed revisions to the GDUFA Science & Research Initiatives for FY 2026 were organized under the same 8 research priority areas as for FY 2025:

- Develop Methods for Generics to Address Impurities such as Nitrosamines
- Enhance the Efficiency of Equivalence Approaches for Complex Active Ingredients
- Enhance the Efficiency of BE Approaches for Complex Dosage Forms and Formulations:
- Enhance the Efficiency of BE Approaches for Complex Routes of Delivery:
- Enhance the Efficiency of Equivalence Approaches for Complex Drug-Device Combination Products:
- Improve the Efficiency of BE Approaches for Oral and Parenteral Generic Products:
- Facilitate the Utility of Model-Integrated Evidence (MIE) to Support Demonstrations of BE:
- Expand the Use of Artificial Intelligence (AI) and Machine Learning (ML) Tools:

Dr. Raney requested input from industry attendees on the proposed revisions, and industry representatives provided insights and recommendations relating to specific priority areas.

- **Develop Methods for Generics to Address Impurities such as Nitrosamines**
  Dr. Krishnan commented on the proposed revisions to this priority area for FY 2026 and suggested that the role of impurities in excipients continues to be an area where ongoing research should remain a priority. All attendees concurred.

  Dr. Vanam advised that it would be helpful if research could help support greater clarity on matters related to reformulations as well as the methodologies for toxicological assessments. Dr. Rege discussed recommendations in the recent FDA Guidance for Industry on Control of Nitrosamine Impurities in Human Drugs, and acknowledged that while bioequivalence pathways are relatively clear for reformulated BCS Class I and II products, that the impact of reformulation on BCS Class IV drug products can be more complex and concurred that understanding this better should be a priority for future research.

  Dr. Lionberger asked industry attendees about their experience and challenges with reformulating products impacted by nitrosamine impurities, and about circumstances that necessitated larger formulation changes. Multiple industry attendees commented that minor reformulations may not adequately address issues with nitrosamine impurities, and that there are inevitably instances where larger formulation changes are needed.

  Dr. Josephson discussed divergence among global regulatory agencies and encouraged prioritizing research to facilitate global harmonization on standards relating to nitrosamine impurities. Dr. Josephson also discussed scientific challenges and knowledge gaps with interpreting the results of mutagenicity assays as part of an assessment of carcinogenicity, and encouraged prioritizing GDUFA research in this area.

- **Enhance the Efficiency of Equivalence Approaches for Complex Active Ingredients**
  Dr. Josephson thanked FDA and supported the proposal to prioritize research focused on facilitating the use of recombinant peptides in generic drug products. Dr. Raney noted that the some of the outcomes from this research on recombinant peptides may also help address regulatory challenges associated with the heterogeneity and complexity of naturally sourced ingredients.

- **Enhance the Efficiency of BE Approaches for Complex Routes of Delivery**
  Dr. Josephson requested clarity about whether the research under Priority Area 4A would address challenges relating to the transition of inhalation products to use propellants with a low global warming potential (LGWP). Dr. Newman clarified that research on LGWP propellants was addressed under Priority Area 5C. Dr. Krishnan agreed with the proposed revision under Priority Area 4A to prioritize research on improved in vivo PK study designs and modeling methods, which would include research on alternatives to traditional methods and designs for charcoal-block in vivo PK studies.

- **Enhance the Efficiency of Equivalence Approaches for Complex Drug-Device Combination Products**
  Dr. Josephson noted that key challenges relating to LGWP propellants may be associated with regulatory policy positions, and requested clarity about the value of prioritizing research in this area. Dr. Luke clarified the research conducted under this priority may help inform regulatory policy.

- **Improve the Efficiency of BE Approaches for Oral and Parenteral Generic Products**
  Dr. Krishnan requested clarity about the classification of research priorities for ophthalmic drug products under Priority Area 6, which focuses on bioequivalence approaches for oral and parenteral generic products. Dr. Lionberger clarified that the ophthalmic products were included here because ophthalmic and parenteral products share a similar regulatory framework, and research in this area focuses on expanding the flexibility of formulation criteria for both classes of products.

Dr. Raney thanked all attendees for their recommendations about research areas that should be prioritized in FY 2026. He also invited attendees to email FDA with any additional feedback relating to the proposed FY 2026 GDUFA Science and Research Priorities so that it can be considered and potentially incorporated into the final version.

10:45 AM – 10:55 AM Discussion of the FY 2026 GDUFA Public Workshop (June 2-3, 2026)

Dr. Raney facilitated a discussion on the FY 2026 GDUFA Public Workshop, noting the meeting is tentatively scheduled for June 2-3, 2026, and will tentatively be a hybrid meeting (in person at FDA White Oak campus, and virtual). However, on June 2-3, 2026, there is an ICH meeting that would interfere with the FY 2026 GDUFA Public Workshop and proposed June 8-9, 2026. Mr. Randazzo anticipated that the new dates would work, and will confirm with Dr. Raney.

Dr. Raney noted that the next bi-annual working group meeting is scheduled for November 10, 2026, and would focus on the topics for the FY 2026 GDUFA Public Workshop.

10:55 AM – 11:00 AM Review of Meeting Outcomes and Proposed Action Items

Dr. Raney offered a brief review of the meeting outcomes and next steps.

- FDA to revise the draft FY 2026 GDUFA Science & Research Priorities document and share it with group
- AAM to facilitate industry review of the draft FY 2026 GDUFA Science & Research Priorities
- FDA and industry attendees to consider topics for FY 2026 GDUFA Public Workshop
- The next bi-annual working group meeting will be on November 10, 2026, to discuss the FY 2026 GDUFA Public Workshop.

Dr. Raney and Dr. Lionberger thanked all the attendees for their participation and concluded the meeting.