

GRX+BIOSIMS CONFERENCE

UNDERSTANDING HOW REIMBURSEMENT CAN IMPACT BLA SUBMISSION STRATEGIES

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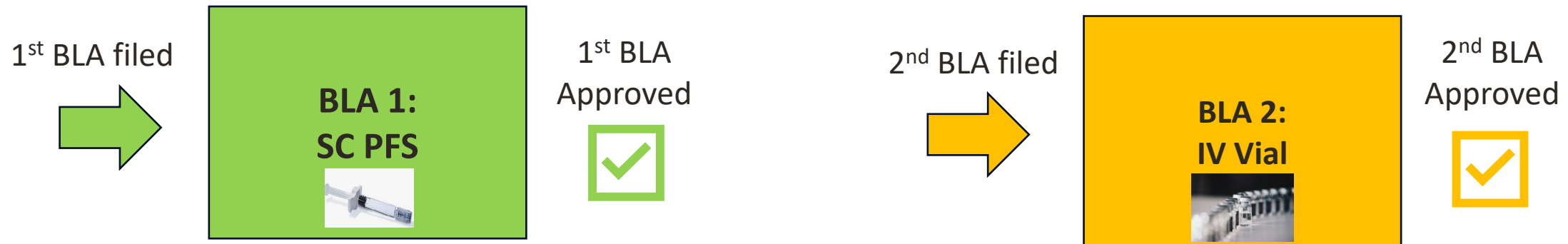
M. Stacey Ricci, M.Eng., Sc.D.
Director, Scientific Review Staff
Office of Therapeutic Biologics and Biosimilars
Office of New Drugs | CDER | FDA

Mustafa Ünlü, Ph.D., J.D.
Director, Policy Staff
Office of Therapeutic Biologics and Biosimilars
Office of New Drugs | CDER | FDA

Possible Scenario for 2 BLAs for Same Drug Substance

Scenario 1

- Applicant submits BLA1 first and later submits BLA2 with additional strengths/presentations after approval of BLA1



Possible Scenario for 2 BLAs for Same Drug Substance

Scenario 2

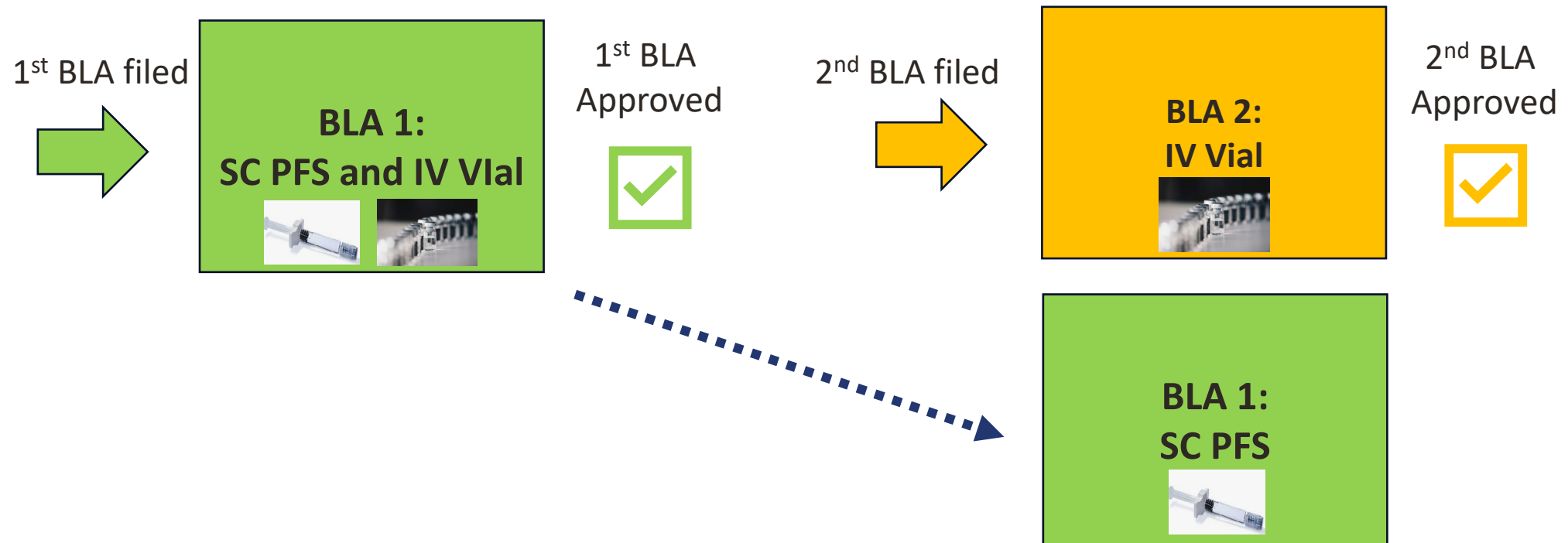
- Applicant submits BLA1 containing multiple strengths/presentations and later submits BLA2 with a subset of the strengths /presentations that are in BLA1



Possible Scenario for 2 BLAs for Same Drug Substance

Scenario 3

- Applicant submits BLA1 containing multiple strengths/presentations. After BLA1 is approved, applicant submits BLA2 with a subset of the strengths /presentations that are in BLA1



Challenges with Splitting a BLA

- Advising sponsors on how to cross-reference information in BLA1 and BLA2
- Coordinating review timelines of supplements to BLA1 with timeline for BLA2
- Coordinating changes to labeling across applications
- Potential PREA challenges
- Other potential challenges, e.g., exclusivity issues due to first interchangeable exclusivity (FIE); orphan drug exclusivity (ODE)

Scenario 3 is Most Challenging

- Sponsor Requests for Early Action on BLA2
- Supplement submission coordination
 - Pending supplements for BLA1 may require approval before taking action on BLA2
 - One case involved 14 supplements submitted to BLA1 while BLA2 was pending, including CMC supplements
- Coordinating timelines between BLAs
 - Same products are both in approved and pending status
- Policy issues
 - Timing of license revocation for product(s) in BLA1
 - Exclusivity issues (some products may be subject to FIE/ODE and/or have FIE)
- Labeling complexities
 - What happens if the reference product updates its labeling while BLA2 is pending
- Potential PREA challenges



Questions?