FY 2020 Generic Drug Regulatory Science Initiatives Public Workshop

Drug-Device Combination Products Breakout Session

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What are Drug-Device Combination Products and What Makes Some of Them *Complex*?

Drug-device combination products are products that have both a drug constituent part and a device constituent part. These products that are regulated by Office of Generic Drugs (OGD) have a primary mode of action (PMOA) of drug.

Complex products are those products that are more difficult to develop generics for due to inherent features, such as complex API (active pharmaceutical ingredient), complex formulations/dosage forms, complex route of delivery, or some other complexity of design – e.g., complex device component.

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What Does OGD Review?

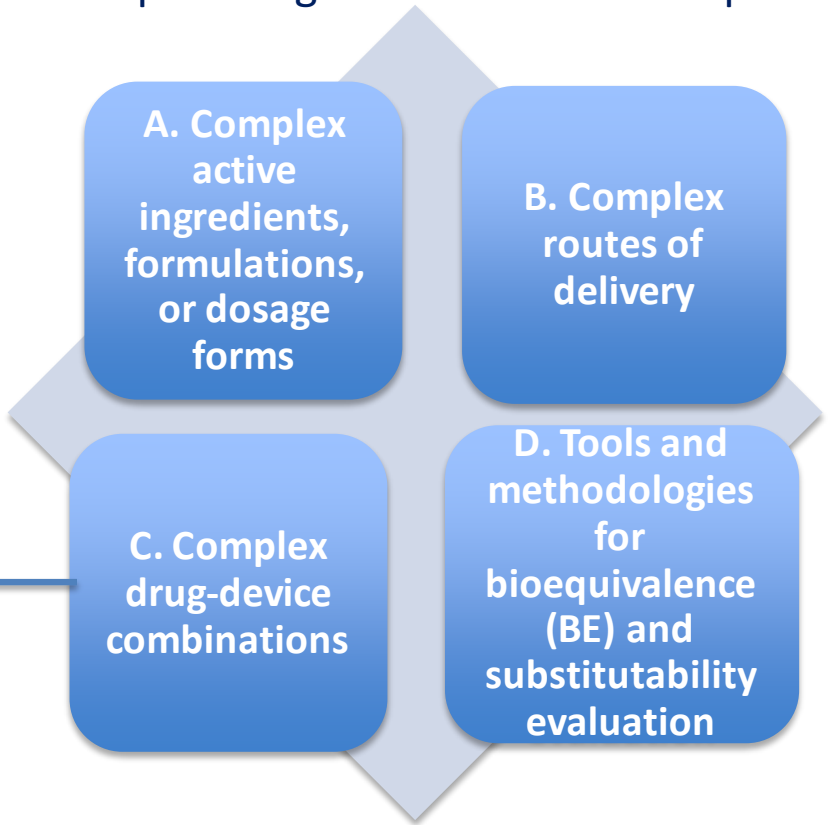
- In addition to any usual drug bioequivalence comparisons, as appropriate, for combination products OGD compares Test and Reference devices and labeling
- The impact of the device on bioequivalence is considered and evaluated as appropriate
- Review Comparative Analysis provided by the applicant and determine whether additional information and/or data are needed

Identifying Research Gaps

1) New device constituents and what considerations do they raise for bioequivalence (BE)?
2) What are important metrics for user interface considerations?
3) What are the relative imports of various labeled “steps” in the use of various specific combination products?
4) What design considerations are vital for certain device constituents in the context of BE?
5) What material considerations should we have for certain device constituents for combination products – impact on BE?
6) What possible future considerations should be evaluated, e.g., software in medical devices constituents and impact on BE?

FY2020 GDUFA Research Science Priorities

that are most relevant to complex drug-device combination products



C1. Evaluate the impact of identified differences in the user-interface from the reference listed drug (RLD) on the therapeutic equivalence of complex generic drug-device combination products

C2. Develop criteria for device performance comparisons that would support a BE demonstration by in vitro methods and eliminate the need for in vivo BE.

https://www.fda.gov/media/132370/download

Expert Discussants

- Markham Luke, MD PhD – FDA, Division of Therapeutic Performance (DTP) - moderator
- Ravi Harapanhalli, PhD - Amneal
- Molly Story, PhD – Sanofi, Medical Device Development Unit
- Roisin Wallace, PhD - Mylan
- Christoph Zauner, PhD - Fresenius-Kabi
- Elizabeth Bielski, PhD – FDA, Inhaled Products Team, DTP – our rapporteur
- Priyanka Ghosh, PhD – FDA, Topical Products Team, DTP
- Bin Qin, PhD – FDA, Complex Injectables & API, DTP
- Kimberly Witzmann, MD – FDA, Office of Bioequivalence
- Bing Cai, PhD – FDA, Office of Pharmaceutical Quality (OPQ), Lifecycle Drug Products
- Dhaval Gaglani – FDA, OPQ, Lifecycle Drug Products

Questions for the Expert Discussants

- For industry members –
  - What are the key gaps in knowledge that could be addressed with targeted research in the context of developing generic drug-device combination products?
  - How will the research facilitate generic product development?
  - Are there any prioritization considerations you wish for FDA to consider when deciding which research projects to pursue?
- For FDA – What review issues or questions have you encountered that you believe can be addressed in the context of FDA's generic drug research program?

Questions from Audience

- Type in questions in the chat box
- Please state your name, title, and affiliation
- Please state your question or comment
- Provide as much context as feasible

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