# Device Considerations from User Interface Perspective: Comparative Analyses

## AAM 2020: GRx+Biosims Complex Workshop

**Session 4: Device Considerations for Complex Drug-Device Combination Products**

**Betsy Ballard, MD**

Division of Therapeutic Performance, Office of Research and Standards
Office of Generic Drugs| CDER | U.S. FDA

November 10, 2020

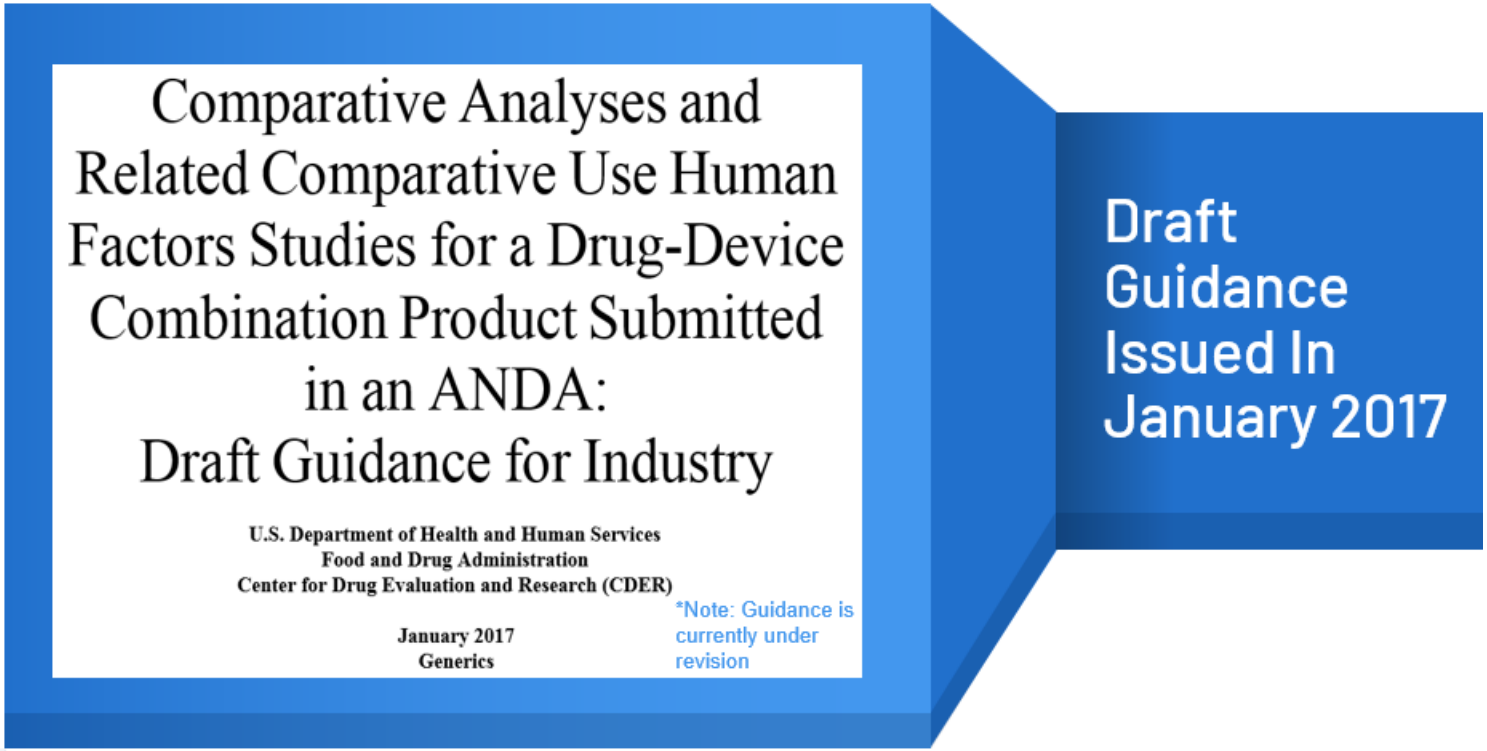
# General Principles

Considerations include, but are not limited to:

- Performance characteristics

  takes into consideration the performance of the device constituent and its interaction and impact on the delivery of the drug constituent

- User Interface


Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA:
Draft Guidance for Industry
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
January 2017
Generics
*Note: Guidance is currently under revision
Draft Guidance Issued In January 2017

# Definitions

**User Interface:** Refers to all components of a product with which a user interacts, such as labeling and packaging, the delivery device constituent part, and any associated controls and displays

**External Critical Design Attributes:** Refers to those features that directly affect how users perform a critical task that is necessary in order to use or administer the drug product

**Critical Tasks:** For example, tasks that if performed incorrectly or not performed at all, would or could cause harm to the patient or user, where harm is defined to include compromised medical care

# Key Points from Draft Guidance

- The design does not have to be identical to the reference listed drug (RLD).
- Differences in the design of the user interface should be adequately analyzed, scientifically justified, and not otherwise preclude approval under an ANDA
- Differences in the design of the user interface should be minimized in early phases of the drug development.
- Certain labeling differences may be allowed (case-by-cases) .
- FDA intends to consider whether the generic combination product can be substituted for the RLD without the intervention of a health care provider and/or without additional training prior to use.

# Additional Key Points

- Baseline assessment for any identified differences occurs during comparative analyses
- Will determine whether additional information and/or data are warranted
  - May include Comparative Use Human Factors Studies
  - Not intended to demonstrate the safety or effectiveness of the proposed generic combination product

# Comparative Analyses

1. **Labeling Comparison:** Side-by-side, line-by-line comparison of the full prescribing information, instructions for use, and descriptions of the delivery device constituent parts of the generic combination product and its RLD.
2. **Comparative Task Analysis:** Comparative task analysis is assessed between the RLD and the proposed generic drug-device combination product looking as the external critical design attributes that directly affect how users perform a critical task. Should be based on the external operating principles of the device.
3. **Physical Comparison of Delivery Device Constituent Part:** Visual, auditory, tactile examination of the physical features (size, shape, feedback) of the RLD, compared to those of the delivery device constituent part of the proposed generic combination product.

# Outcomes of Identified Differences

Any identified differences between the user interface of a proposed generic combination product and its RLD in the context of the *overall risk profile* of the product should be identified as:

- **No Differences**
- **Minor Differences**
  - Guidance describes a design difference as minor if the differences in the user interface of the proposed generic combination product, in comparison to the user interface of the RLD, do not affect an external critical design attribute
- **Other Differences**
  - FDA may not view a design difference as minor if any aspect of the threshold analyses suggests that differences in the design of the user interface of a proposed generic combination product as compared to the RLD *may* impact an external critical design attribute that involves administration of the product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