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Pre-ANDA Opportunities for Generic Drug-Device Combination Product Development

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Office of Generic Drugs| CDER | U.S. FDA

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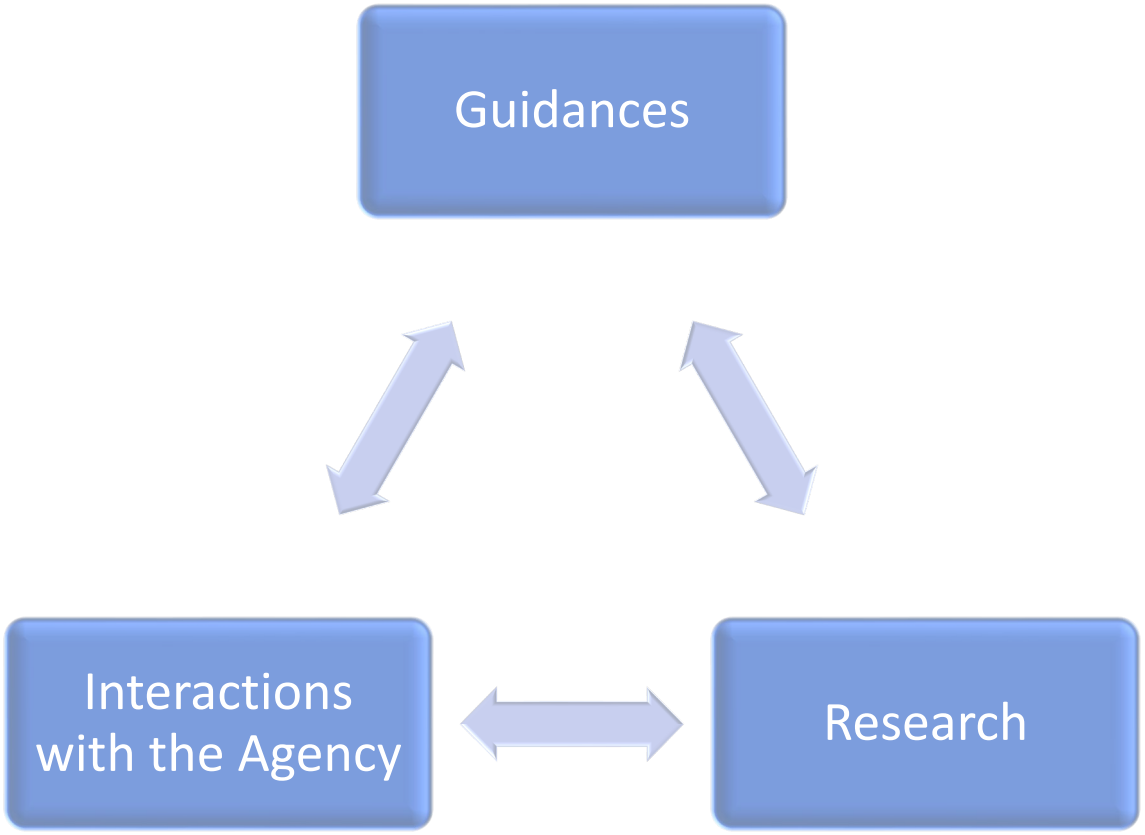
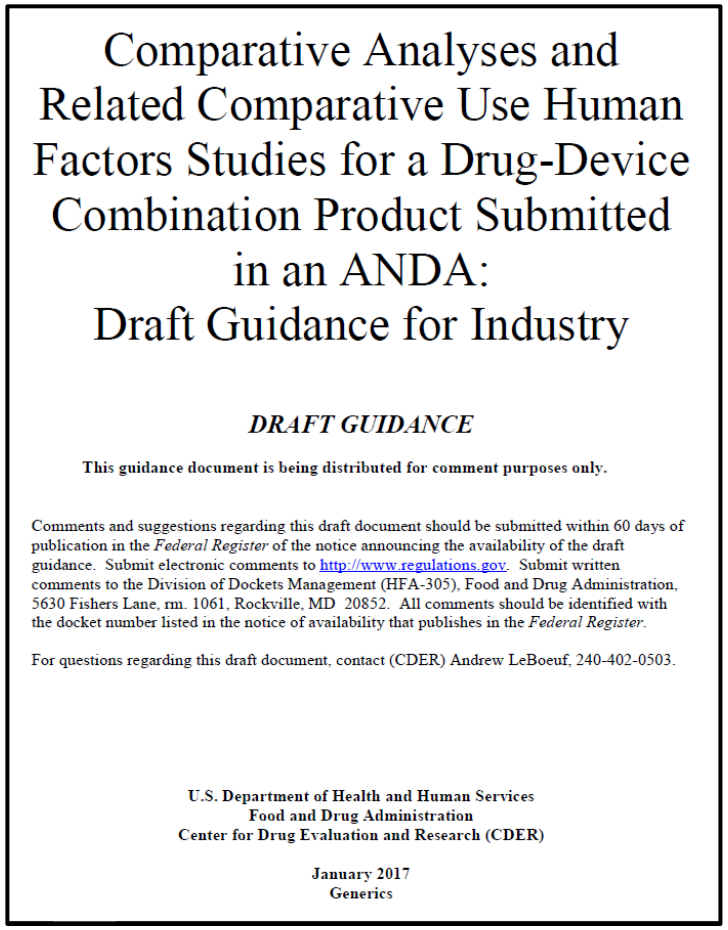
OGD's Pre-ANDA Program

- The pre-ANDA program is designed to:
  - Assist applicants in developing more complete submissions
  - Promote more efficient and effective ANDA assessment processes
  - Reduce the number of assessment cycles
  - Facilitate approval of complex generic drug products



General Guidance for Generic DDCP Development



Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA: Draft Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Andrew LeBoeuf, 240-402-0503.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

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Generics

- Comparative analyses should be conducted during the product development phase to understand similarities/differences of proposed generic user interface as compared to the reference listed drug.
- Potential applicants are encouraged to submit comparative analyses and any user interface questions to FDA for review through the Pre-ANDA Program.
- Access the guidance at: https://www.fda.gov/media/102349/download

Product-Specific Guidances (PSGs): Semaglutide; NDA 215256[1] as an Example

Device Subheading

Device:
The RLD is presented in a prefilled autoinjector. The autoinjector is the device constituent part.

Recommendations to Consider

FDA recommends that prospective applicants examine the size and shape, the external critical design attributes, and the external operating principles of the RLD device when designing the test device including:

- The single-use, single-dose format of the autoinjector device
- Inspection window
- Needle gauge and length

User Interface Assessment Subheading

User interface assessment:
An abbreviated new drug application for this product should include complete comparative analyses so FDA can determine whether any differences in design for the user interface of the proposed generic product, as compared to the RLD, are acceptable and whether the product can be expected to have the same clinical effect and safety profile as the RLD when administered to patients under the conditions specified in the labeling. For additional information, refer to the most recent version of the FDA guidance for industry on *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*.[a]

[1] Excerpt from draft guidance on Semaglutide (Nov 2023)

Meetings, Correspondences, and Other Opportunities to Interact with FDA

- Controlled Correspondences (CCs)[1] to evaluate user interface; response within 60 days
- Product development meetings (PDEVs)[2] for multiple questions about product development; meeting held within 120 days
- Questions regarding comparative use human factors (CUHF) studies may be submitted in either PDEV or CC (typically respond within 120 days)
- Pre-ANDA submissions regarding device user interface should generally include 1) complete comparative analyses, 2) samples of the proposed generic and reference product, and 3) specific questions
- Workshops and conferences
  - CDER Small Business & Industry Assistance (SBIA), Center for Research on Complex Generics (CRCG), etc.

[1] Guidance for Industry. Controlled Correspondence Related to Generic Drug Development (March 2024) https://www.fda.gov/media/164111/download

[2] Guidance for Industry. Formal Meetings between FDA and ANDA Applicants of Complex Products Under GDUFA (Oct 2022). https://www.fda.gov/media/107626/download

Generic Drug Science and Research Program

- FDA hosts an annual Generic Drug Science and Research Initiatives Public Workshop, and FDA considers public comments in developing research priorities for the fiscal year
- Enhancing the efficiency of equivalence approaches for complex DDCPs is one of the current priorities
  - Includes improving data analysis approaches for assessing comparative task analysis and CUHF studies
- Current and completed projects in support of this priority include:
  - A contract to conduct CUHF studies to assess the impact of differences between DDCP user interfaces [1]
  - Development of a DDCP taxonomy[2]
  - Formative research to understand the impact of generic substitution for various patient and caregiver populations[3]
  - More information available at OGD's Science and Research website: https://www.fda.gov/drugs/generic-drugs/science-research

[1] Contract 75F40123D00028-75F40123F19001 with Core Human Factors, Inc.

[2] Grant 1U01FD007360 with University of Detroit Mercy

[3] Contract HHSF223201810113C with RTI International


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