# Complex Drug-Device Generic Combination Products

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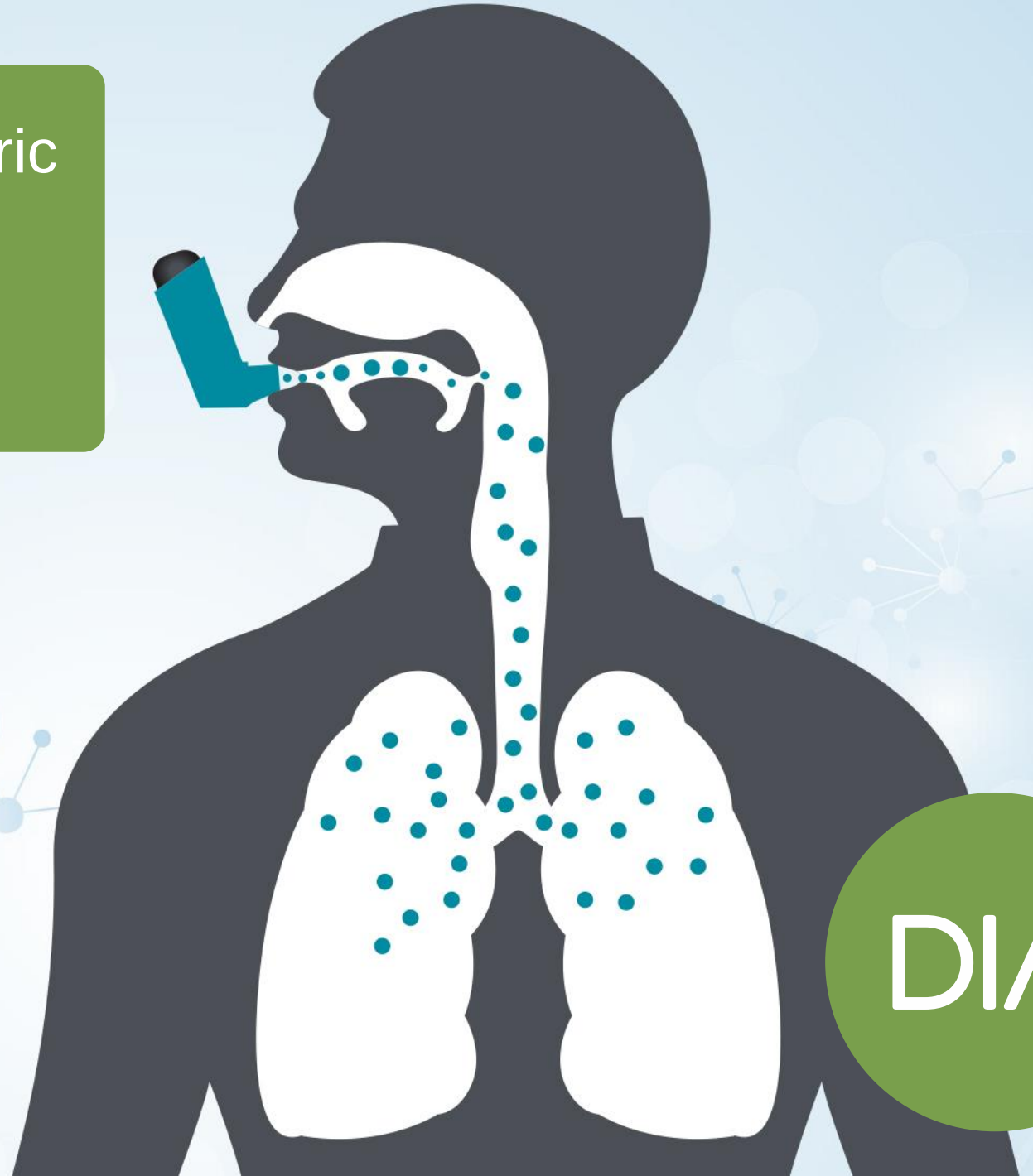

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# Combination Drug Products and Generic Drug Science

## Closing Remarks

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# Speaker Disclaimer

The opinions and conclusions expressed in this forum are the viewpoints of the speaker(s) and do not necessarily reflect the official position of the U.S. Food and Drug Administration.

# Key Goals of the Workshop

- Help potential ANDA applicants navigate the evolving regulatory environment around combination products
- Identify key scientific challenges in the development of generic combination products
- Increase access to high quality generic versions of complex products

# Three Points to Take Home

- Know the current FDA requirements and recommendations for combination products to meet drug and device GMPs.
- Read the draft guidance *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA: Draft Guidance for Industry* (January 2017), and consider the comparative analysis from the draft guidance in the development of all your combination products.
- Use the controlled correspondence and the pre-ANDA meeting process to finalize your device design before conducting your pivotal bioequivalence studies for complex products.

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