Introductory Remarks

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Non-clinical Immunogenicity Assessment of Generic Peptide Products: Development, Validation, and Sampling

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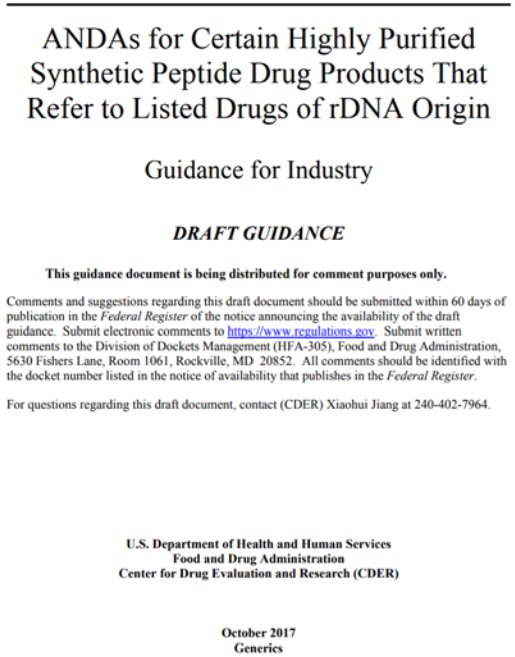
Increase Access to Complex Generics

- Peptides less than 40 amino acids remain regulated as drug products
  - They did not transition to BLA on March 23, 2020
- ANDAs may be submitted for these reference products

Scientific and Regulatory Challenges

- Our GDUFA supported science and research program has targeted the regulatory and scientific challenges related to developing generic versions of peptide products

Regulatory Advances Based on Science



ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin

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DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.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be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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 https://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 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) Xiaohui Jiang at 240-402-7964.

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

October 2017
Generics

- Development of analytical methods to characterize peptide impurities was a critical piece of this regulatory advance
- December 28, 2020: first glucagon generic was approved

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM578365.pdf

Scientific Challenges on the Path to ANDA Approval

- Immunogenicity assessment for generic peptides of synthetic origin referencing a peptide of recombinant origin
  - This has been a GDUFA II research priority
  - Today you will hear about research outcomes
  - Today you will **engage** with FDA on how to implement non-clinical immunogenicity assays in generic product development and ANDA submission

Workshop Goals

- Discuss technical and regulatory challenges with non-clinical immunogenicity assays
- Explore future research directions for standardizing the non-clinical immunogenicity assays for generic peptide products and establishing best practices

Next Steps for Workshop Participants

- Use what you have learned from this workshop in your generic drug development programs
- Use the pre-ANDA meeting process for complex products to resolve scientific issues before ANDA submission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