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GRX+BIOSIMS

The Suffix, What is it Good for?

Pharmacovigilance, Practical Experience and Emerging Considerations

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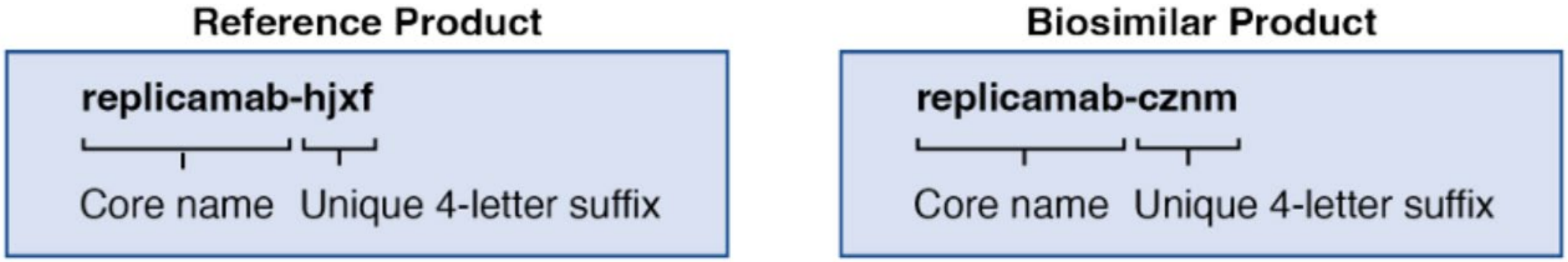
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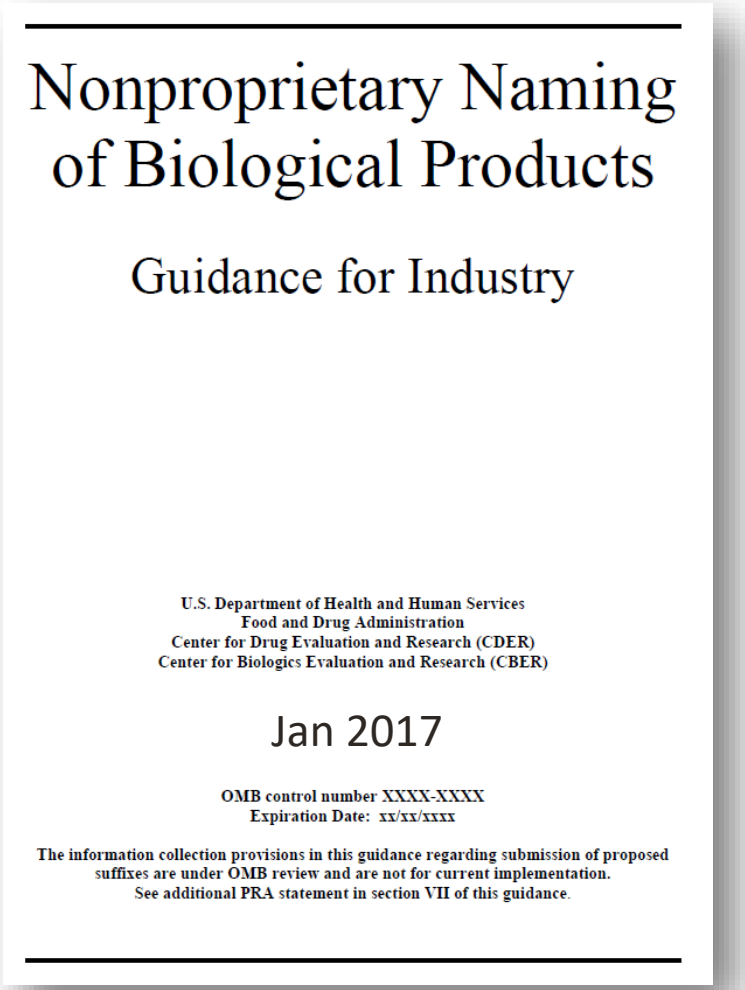
No conflicts of interest to disclose.

FDA's Naming Convention for Biological Products

- FDA designates a nonproprietary name that is a combination of the **core name + 4-letter suffix**
- For biosimilar and interchangeable biosimilar products, the core name is the same as that of its reference product



Why Create a New Naming System?



Nonproprietary Naming of Biological Products

Guidance for Industry

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

Jan 2017

OMB control number XXXX-XXXX
Expiration Date: xx/xx/xxxx

The information collection provisions in this guidance regarding submission of proposed suffixes are under OMB review and are not for current implementation.
See additional PRA statement in section VII of this guidance.

- The goal of the naming convention was to create a nonproprietary naming system to distinguish biosimilars and other biological products containing related drug substances:
  - To enhance pharmacovigilance
  - To facilitate safe use (i.e., minimize inadvertent substitution)

- Application of the naming convention to all* biological products licensed under the PHS Act was intended to:
  - Avoid inaccurate perceptions of the safety and effectiveness of biological products based on their licensure pathway
  - Encourage routine use of designated suffixes in ordering, prescribing, dispensing, and recordkeeping practices

*FDA issued draft guidance in March 2019 that exempts reference products licensed without a suffix.

Assessing if Goals of Adding a Suffix Have Been Met

- Has the suffix enhanced pharmacovigilance tracking of adverse events?
  - **Active Surveillance Systems** (electronic health care records)
  - **Passive Surveillance Systems** (spontaneous event reporting)
- Does the suffix avoid inaccurate perceptions of the safety and effectiveness of biological products based on their licensure pathway?
- Does the suffix facilitate safe use in pharmacy practice (i.e., minimize inadvertent substitution)?



Today's Session Panelists and Presentations

- **Danijela Stojanović, FDA**
  - Sentinel Post-Marketing Surveillance: Safety Signal Identification for Biosimilars
- **Monica Muñoz, FDA**
  - Suffix Use for Biosimilar Product Identification in Post-Marketing Adverse Event Reporting
- **Mariana Socal, Johns Hopkins University**
  - Naming Convention, Interchangeability, and Patient Interest in Biosimilars
- **Mary Jo Carden, Carden Associates**
  - What the Suffix? Are they Relevant Today?
- **Mustafa Ünlü, FDA**