

# FOLLON-ON BIOLOGIC

- **EPPIC – EMERGING TRENDS & OPPORTUNITIES IN LIFE SCIENCE**

- **Session 3: Current Trends in Biosimilars**

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- Attorney in FDA Laws & Regulations....25 years

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FDA Advisory to biomedical companies

# FOLLOW-ON BIOLOGIC

**Drug** (21 U.S.C. § 321(g)(1)(B),(C)), Federal Food, Drug, and Cosmetic Act (*FDCA*):

“**DRUG**” as an article intended for use in the diagnosis, cure, treatment or prevention of disease in man or other animals; and articles (other than food) intended to **affect the structure or any function of the body of man** or other animals.

full (b)(1) NDA>>>new drug

505(b)(2) NDA>>>new use of approved drug moiety

505j >>>abbreviated NDA generic

**Biologic** (42 U.S.C. § 262(I)), Public Health Service Act (*PHS*)-

**BIOLOGIC**” - as “**a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product**, .... applicable to the prevention, treatment, or cure of a disease or condition of human beings.”

**BLA >>> Biological Application (BLA= full NDA)**

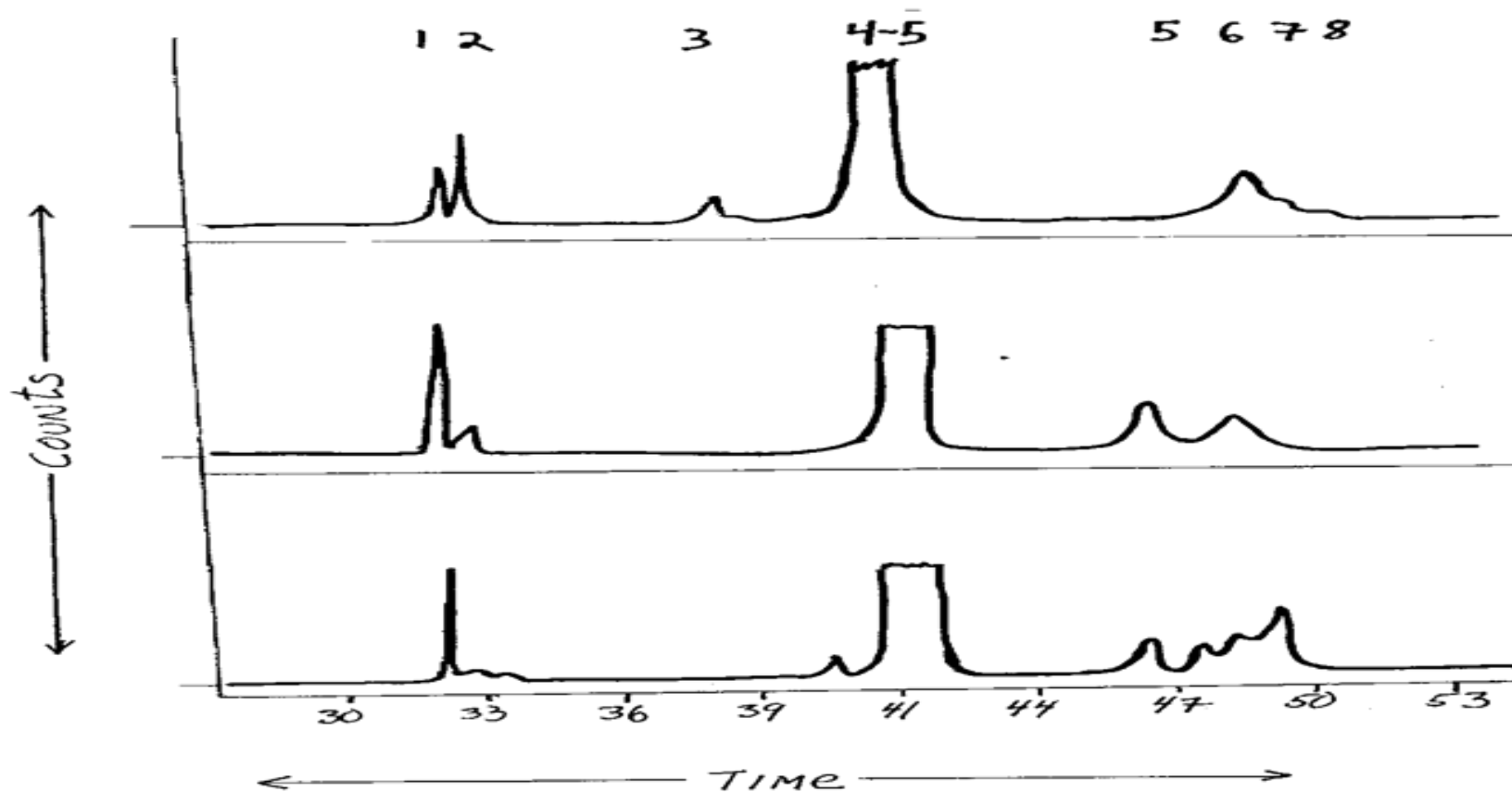
# FOLLOW-ON BIOLOGICS

- **DEFINITIONS:**

- **Follow-on Biologics:** implies next generation product that may or may not be improved over originator product, but is intended to compete with the it. **Commodity Pricing**
- **Follow-on ‘Branded’ Biologics:** implies an improved next generation product usually incorporating new delivery technologies. **Speciality Pricing**
- **Biosimilars:** implies a relationship, but not that it is identical to (same as), but intended to compete with the originator product. **Commodity Pricing**
- **Biogenerics:** implies sameness to and substitutability for the originator product. **Commodity Pricing**

# Follow-on Biologics

**Capillary Zone Electrophoresis - Separates rhGH variants according to their mass charge ratio**



# FOLLOW-UP BIOLOGICS

## **No Claim of Interchangeability (BX):**

- Chemistry comparative data
- One comparative bioassay
- PK/bioavailability study to listed drug, no PD required
- Human immunogenicity data during clinical trial
- Efficacy data required (1 study)

**>> all biosimilars  
thusfar approved by FDA**

## **Claim of interchangeability (AB):**

- Chemistry rigorous comparative data
  - Two comparative bioassays
  - Rigorous comparative PK/PD to listed drug
  - Human immunogenicity data
  - Efficacy not required
- >>not likely for the next  
5-10 years**

# FOLLOW-ON BIOLOGICS

- **Biosimilar Product Development strategy**
  - **Develop 1<sup>st</sup> generation biosimilar biologic drug, which is similar to original drug.**
    - *Original drug a lyophilized formulation requiring reconstitution, removal from vial with syringe for injection.*
  - **Develop 2<sup>nd</sup> generation biosimilar biologic drug using new delivery technology, but now using your first generation as the originator drug.**
    - *This converts 2<sup>nd</sup> generation biosimilar drug into a follow-on 'brand' biologic drug with administrative exclusivity and intellectual property protection*