FDA Public Meeting:
Approval Pathway for Biosimilar and Interchangeable Biological Products

May 11, 2012

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INDUSTRY ORGANIZATION

The Biotechnology Industry Organization

- Over 1,100 members, including biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations
- 91% of members have <25M annual revenue
- Non-profit trade association founded in 1993
- Close involvement in biosimilars debate since 2002 (www.bio.org/category/biosimilars)

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Key Issues

1. Interchangeability
2. Naming and Labeling
3. Confidentiality of Information
4. Reference Product and Non-U.S. Data
5. Patent Certification
6. Transition Products
7. Additional Q&As and Guidance for Implementation of BPCIA

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Interchangeability should be clearly distinguished from biosimilarity

- Statutory approval criteria for interchangeability are considerably more extensive than those for biosimilarity
- It is particularly important to consider a number of factors for interchangeability, including:
  - Complexity of product structure and formulation
  - Degree of structural similarity between reference molecule and biosimilar
  - Mechanism of action
  - Safety and immunogenicity profile
  - Therapeutic index
  - Post-marketing efficacy and safety data
  - Overall risk-benefit profile
  - Intended therapeutic area
  - Route of administration
  - Patient factors
  - Switching studies
  - Outlier effects
  - Product drift
- FDA has acknowledged that interchangeability is a higher bar than biosimilarity, and this should be reflected in the standards set by FDA

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Naming and Labeling: FDA should adopt policies and issue guidance on these topics

- Naming policies should:
  - Facilitate identification of exact product received by patient
  - Address/ensure brand and distinguishable non-proprietary name
- Standardized and internationally harmonized naming system may have value but should be consistent with ensuring robust tracking and tracing of biologics
- Labeling policies should ensure that biosimilar product labels:
  - Contain essential scientific information specific to the biosimilar product
  - Are informative and accurate
  - Avoid misleading and false statements
  - Have adequate directions for use
  - Address safety, warnings, and precautions

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FDA Must Ensure Confidentiality of Information

- FDA regulations on public disclosure of BLA information must be updated for consistency with BPCIA
- The innovator company's confidential commercial and trade secret information must be protected from intentional or inadvertent use or disclosure in the 351(k) review and approval process
- 351(k) application must stand on its own; FDA approval must be based upon 351(k) data and publicly-available information regarding the reference BLA
- Procedures should assure proper review of 351(k) applications and avoid potential disclosure or inappropriate reliance upon reference BLA data

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Caution Regarding Use of Data from Non-U.S. Comparator Products

- BPCIA mandates that a biosimilar be evaluated against only one, U.S.–licensed, reference product
- Data comparing to a foreign product should only be accepted as support for an application when both foreign and domestic product are released by the same license holder/manufacturer
- Introducing a second comparator product raises additional scientific questions and necessitates a highly cautious approach
- Additional clarity is needed to fully address the type of bridging studies that could support biosimilar approval using data from non-U.S. comparator products

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Patent Certification

- FDA has an important role in assuring full compliance with the BPCIA to maintain the balance of interests in the BPCIA

- The BPCIA requires that a 351(k) applicant provide a copy of the application and manufacturing process information to the reference BLA holder within 20 days of the application being accepted for review
  - FDA should require 351(k) applicants to certify that they will provide this information to the reference BLA holder
  - FDA should refuse to file a 351(k) application without a certification

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Transition Products

- Address the timeframe and process for implementation of the provision deeming a biologic approved under section 505 of the FFDCA to have an approved BLA in 2019

- Official list is needed of biological products/product classes, approved under FFDCA, which will be subject to transition

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Additional FDA Guidance

- Interchangeability
- Non-proprietary Naming
- Labeling
- Sample Retention
- Quality Attributes that Shift over Time
- Product Specific Guidances

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Additional FDA Q&As

- 351(a) v 351(k) Pathway: Identify the factors FDA will consider in determining whether an application submitted under 351(a) is not a full BLA, and refusal to file policy

- Patent Certification: Address the process for assuring 351(k) applicant compliance with the BPCIA patent provisions and the form to be used for 351(k) submission

- Protection of confidential BLA information: Address the procedures to be employed to assure that non-public BLA information is not accessed for purposes of 351(k) review or approval

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