EVOLVING SUPAC FOR TODAY'S COMPLEX PRODUCTS – INDUSTRY PERSPECTIVE

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APOTEX

ESTABLISHED CONDITIONS

- **Uptake of Established Conditions (ECs) in ANDAs has been low compared to NDAs……Why?**
  - ECs require a deep understanding of risk-based categorization and regulatory strategy. Many generic manufacturers, especially smaller firms, may lack the resources or expertise to implement these effectively

  - Unlike innovator companies, generic manufacturers often:
    - Operate under tighter margins
    - Focus on cost-efficiency and speed to market
    - Avoid complex regulatory strategies unless there's a clear ROI
    - ICH Q12 offers long-term flexibility, but the upfront effort may not be justified for many ANDA holders.

ESTABLISHED CONDITIONS (CONT'D)

- Effective use of Q12 tools depends on a robust Pharmaceutical Quality System (PQS), and many ANDA sponsors rely on CMOs with independent PQS systems

- Lack of Clear Guidance for Generics…..Although FDA guidance exists, ANDA applicants often find:
  - Ambiguity in defining ECs for generic products
  - Uncertainty in how to structure PLCM documents
  - Limited examples or case studies tailored to generics

COMPARABILITY PROTOCOLS

- Greater uptake amongst generic applicants as compared to ECs
- Simpler concept for generic applicants to consider incorporating into an ANDA, or submit under a PAS post-approval, as it is a stand-alone document for a specific change
- ANDA sponsors find it to be a useful tool to define up front the supporting data that would be required for a particular change, and possibly reduce the filing category post-approval;
- In cases where a reduced filing category is not granted, the up front assessment of supporting data requirements is still beneficial to efficiently prepare for submission of the change

POST-APPROVAL REQUIREMENTS FOR NASALS & MDIS

- As there is often uncertainty around supporting data requirements for changes to these types of products, the case studies presented by the Agency are helpful

- Industry would also welcome formal guidance documents for post-approval changes for these and other types of complex products

CLOSING THOUGHTS….

- Opportunity exists for expanded use of EC's for generics
- Comparability Protocols offer a strategic advantage for generic applicants by streamlining post-approval changes
- Mechanisms to seek FDA feedback on post-approval filing requirements not currently covered by guidance (ex/ Controlled Correspondence) are useful, as are Case Studies such as the ones presented in this session….additional formal guidance would be beneficial