Issues and Updates in Combination Products Regulation

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Moderated by **Nathan A. Brown**, Partner, Akin Gump Strauss Hauer & Feld LLP

Combination Products Update

FDLI Annual Conference
Washington, DC
May 2-3, 2019

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Associate Director for Policy
Office of Combination Products
U.S. Food and Drug Administration

- A combination products regulatory program
- Policy Developments
- Combination products & combined use

A regulatory program

- Cures Act & FDA/stakeholder alignment
- Coordination, consistency, predictability, leveraging and risk-based approach
- Process/policy: SMGs 4101 and 4103
- Monitoring and oversight (PDUFA VI and beyond)
- Socialization and training: working together to stay on track

Developments

- Jurisdiction
  - Part 3 amendments pending final rule
  - Further guidance
- Premarket
  - Premarket pathways draft guidance (comment period closing May 7th)
  - Coming soon—human factors, bridging, reliability, presubmissions/combination product agreement meetings
- Postmarket
  - Postmarketing safety rule implementation
  - CGMP flexibilities

Combined use products

- Where do you fit?

  "Cross-labeled" combination products, devices referencing drugs, devices for class-based combined uses, general use devices . . .

- Why does it matter?
  - Ensuring safety and effectiveness
  - Innovation and competition considerations

- Digital health—regulatory conciliation/consistency
  - Mobile medical applications (MMA) /clinical decision support software (CDS)
  - Prescription drug use related software (PDURS)

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