



Food and Drug Administration Safety and Innovation Act (FDASIA) Overview

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Brief history of user fees

- Prescription Drug User Fee Act, or PDUFA, was first authorized in 1992
- Medical Device User Fee Act, or MDUFA, was first authorized in 2002
- Each is reauthorized every 5 years
- Provide steady and reliable funding for FDA's medical product review
- “Must pass” legislation – attracts policy riders

The process that led to FDASIA

- Reached consensus surprisingly early
- Bipartisan commitment from leadership in both chambers to move legislation in early Spring
- FDA negotiators and pharmaceutical industry led the way by wrapping up negotiations early
- Other stakeholders had a greater voice in the process

Early stakeholder engagement

- Due to a 2007 mandate from Congress, FDA met with stakeholders during industry negotiations
- Led to some stakeholder interests being addressed early and funded under user fee agreements
- Greater transparency

Environment going into FDASIA

- FDA resources have not kept pace with increasing responsibilities
- Unprecedented advancements in science and technology
- FDA shifting role in an increasingly globalized market
- Concerns from stakeholders about speed of approvals and impact of regulation on innovation

What ended up in the bill?

- Steady, reliable funding for FDA medical product review
- Two new user fees – for generic drugs and biosimilars
- Preserved the approval standard that has served patients and industry well for decades
- Critical new authorities to address public health challenges

Key elements of FDASIA

- Early communication with industry
- Patient engagement
- Risk-benefit
- Encouraging drug innovation
 - Accelerated approval
 - Breakthrough therapies
- New generic drug user fees
- New biosimilars user fees

Key elements of FDASIA

- Drug supply chain security
- Drug shortages
- Pediatric drug testing
- Antibiotic development

Looking forward

- Implementation is well underway
- Opportunities for you to be involved
 - Monitor Federal Register notices for public meetings and opportunities to comment
 - Patient-focused drug development initiative – 10/25/12
 - Medical device postmarket surveillance system – 9/10/12
 - FDA Office of Special Health Issues
 - Go to www.fda.gov and for updates
- Policy issues not included in FDASIA still under consideration

Conclusion

- FDASIA contains many important elements:
 - FDA will get steady, reliable user fee funding for the next five years
 - The approval standard that has well-served patients and industry was preserved
 - Critical authorities, such as those to address the challenges of globalization and encourage drug innovation were enacted

Any questions?

