



MDUFA Reauthorization Process

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Overview

- Statutory requirements



- Participants



- Timeline



Congress provided the road map

- FDA Safety and Innovation Act of 2012 specifies the MDUFA reauthorization process requirements
 - Same requirements as established in the FDA Amendments Act of 2007
- FDA implements the law's provisions on behalf of the Secretary of HHS
- Key principles: transparency and participation



Specific Requirements

- Consultation
 - House and Senate authorizing committees
 - Scientific and academic experts
 - Health care professionals
 - Patient and consumer advocacy groups
 - Regulated industry
- Prior Public Input
 - Federal Register Notice requesting public input
 - Today's public meeting
 - Public comment period of 30 days (docket at www.regulations.gov)
 - FDA posts comments on www.fda.gov

Specific Requirements (cont'd)

- Development of draft recommendations
 - Negotiations between FDA and regulated industry
 - Meeting minutes that summarize substantive proposals and significant controversies or differences of opinion, and their resolution, are publicly available on www.fda.gov
 - Ongoing consultation: FDA holds monthly meetings with patient and consumer advocacy groups during negotiations
- Public review of draft recommendations
 - Present draft to House and Senate committees
 - Publish draft recommendations in the Federal Register
 - Provide 30-day public comment period (docket)
 - Hold a public meeting at which public may express views
 - After considering comments, revise recommendations as necessary

Specific Requirements (cont'd)

- Transmit the final recommendations no later than January 15, 2017
 - “Commitment Letter” (performance agreements)
 - Proposed statutory language (includes fee amounts)
 - Summary of comments received and any changes made to draft recommendations in response to comments



Participants in Negotiations

- FDA, with support from HHS
 - Program managers and technical experts
 - Financial, administrative, and legal support experts
- Regulated industry
 - FDA invites national associations who we believe best represent medical device manufacturers who may be subject to fees under the negotiated agreement.
 - AdvaMed – Advanced Medical Technology Association
 - Medical Device Manufacturer’s Association (MDMA)
 - Medical Imaging Technology Alliance (MITA)
 - American Clinical Laboratory Association (ACLA)

Projected Timeline

