Regulatory Education for Industry (REdI):
GENERIC DRUGS FORUM

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GDUFA Implementation Update

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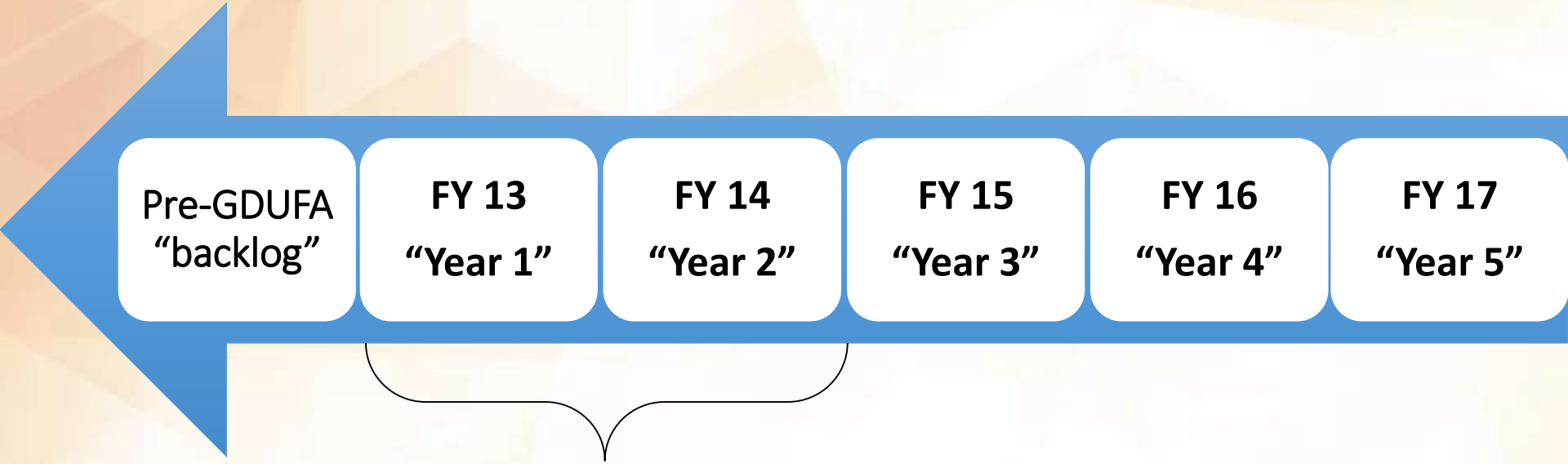
GDUFA Overview

- GDUFA review performance goals
- GDUFA's design: Lay foundation, then ramp up performance
- Years 1 and 2: Restructuring of generic drug program
- Unintended consequences of GDUFA
- Development of workarounds for pre-Year 3 workload
- Next Steps
- Expiration of GDUFA I

GDUFA Submission Cohorts

Use Original ANDAs as an example



- Take action on 90% by end of Year 5
- Expedite review of PIV
- Maintain productivity to extent possible given hiring, training, program and system development activity
- Take action on 60% within 15 months of submission
- Take action on 75% within 15 months of submission
- Take action on 90% within 10 months of submission

GDUFA Years 1 and 2

Years 1 and 2

- **Deep, foundational restructuring to prepare for goal dates in Year 3**
- **A "perfect storm"**
  - **Moved to White Oak**
  - **Reorganized OGD and made it a Super Office, on par with OND**
  - **New business processes in OGD, CDER and across Agency**
  - **New staff**
  - **New IT platform**
  - **2x expected workload**
  - **Oct. 1, 2014 – incoming submissions with goal dates for the first time**
- **Still need to tie up loose ends, but no additional restructuring is anticipated**

Thank you for your patience and understanding. We appreciate you hanging in there with us.

Development of workarounds…

- To address unintended consequences:
  - Industry has strong concerns re productivity and communications for pre-Year 3 submissions
  - Some of these submissions are long pending
  - You want them approved
  - But they lack robust GDUFA goals (See Slide 2)
  - Flash Point – Issuance of “Communications with Industry” MAPP
  - Since then, intensive consultation with industry to accurately diagnose problem and develop impactful workarounds

Big Picture for Year 3

- Hit goal dates AND attack pre-Year 3 workload
- Improve not only communications, but also performance
- Goals:
  - “Move the freight”
  - Focus on approvals, not actions
  - Don’t let big first generics slip through the cracks

Key Initiatives

- **Assign Target Action Dates (TADs) to all pre-Year 3 submissions. (With caveats, and not all at once. See next slide.)**
- **Base TADs on workload management factors, with one exception: For big first generics, assign TADs roughly corresponding with expiry.**
- **In early CY15, start notifying applicants of TADs.**

Key Initiatives (continued)

- **“Launch planning updates” for big first generics 6 and 3 months before TAD.**
- **Certain other pre-launch “go/no go” communications.**
- **Iterative, “real-time communications” re deficiencies in current review cycle. Already started in CMC, scale this out to Bio next.**
- **Finally, update Communications with Industry MAPP to formalize and clarify these changes.**

Looking Ahead

- After extensive consultation with industry, FDA finalized a new approach to pre-Year 3 workload in December, 2014.
- We listened, and worked hard to be responsive and flexible.
- These are major changes.
- Operational, legal, training and other work is underway.

Looking Ahead (continued)

- We have started to notify applicants of TADs.
- Already using "real time communications" to pursue AP, not CR.
- We intend to "move the freight" on all pre-Year 3 submissions by the end of FY17.
- This dramatically exceeds our GDUFA commitments, but is the right thing to do for public health.

GDUFA II

- GDUFA I expires September 30, 2017
- Benefits of GDUFA
  - GDUFA, by design, yields ROI beginning this year: Increased stability, predictability and productivity
  - You can already see the impact for Year 3 submissions
  - We built the machine, and are cranking it up
  - We are confident
- Risk of failure to timely reauthorize
  - RIFs
  - Severe business disruption
  - Reduced access to affordable, quality medicines

Questions?

Evaluation: surveymonkey.com/s/GDF-D1S4