



From the Director

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GPhA Fall Technical Meeting
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Messages

- Accomplishments
- Progress on Initiatives
- User Fee Negotiations Update



Reorganization

New Divisions

- Division of Chemistry-IV
- Division of Bioequivalence-II
- Division of Microbiology
- Division of Clinical Review



Accomplishments

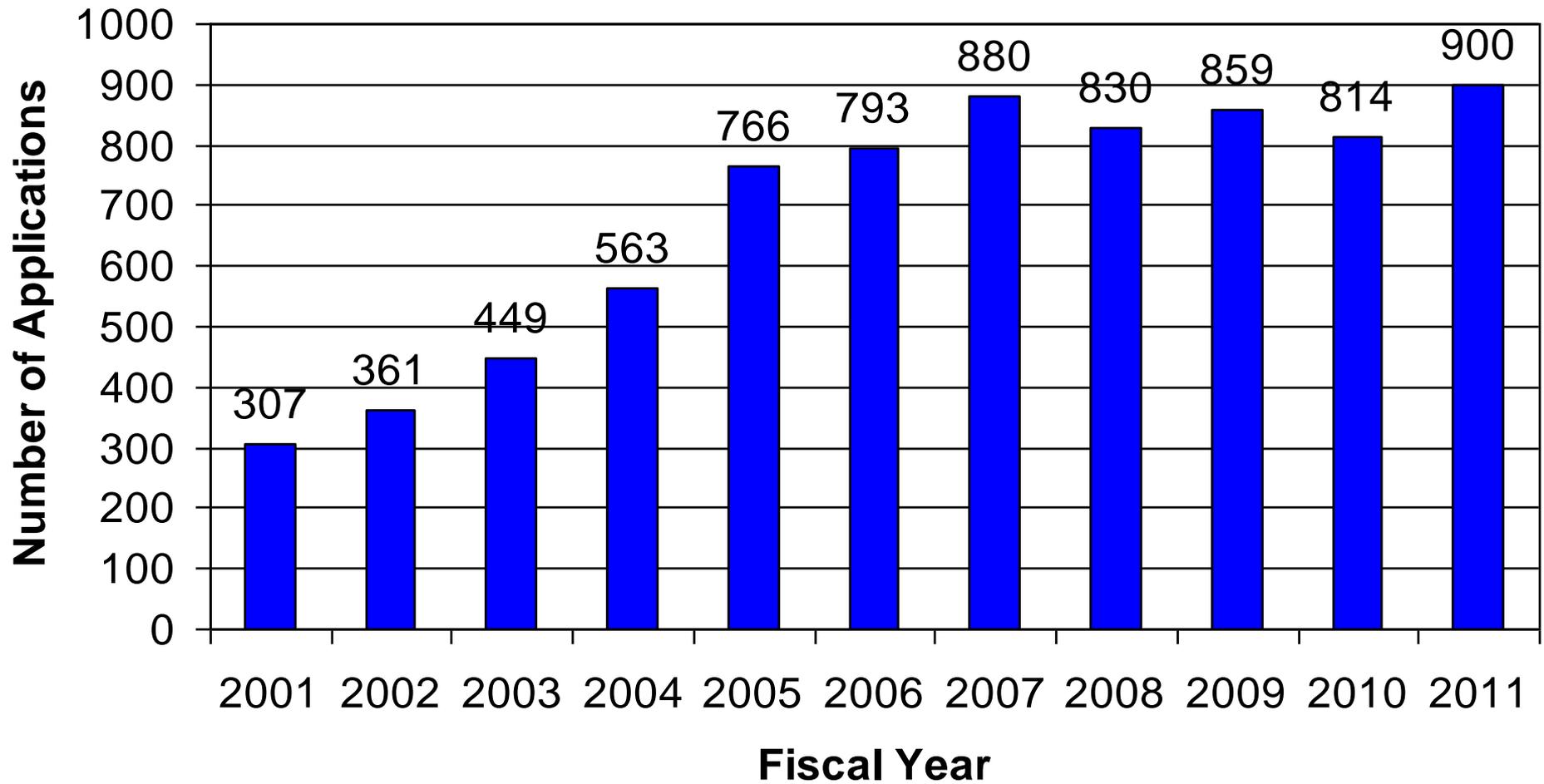
First Generic Approvals

- 106 Approvals
- 29 Tentative approvals

Total approvals = 457

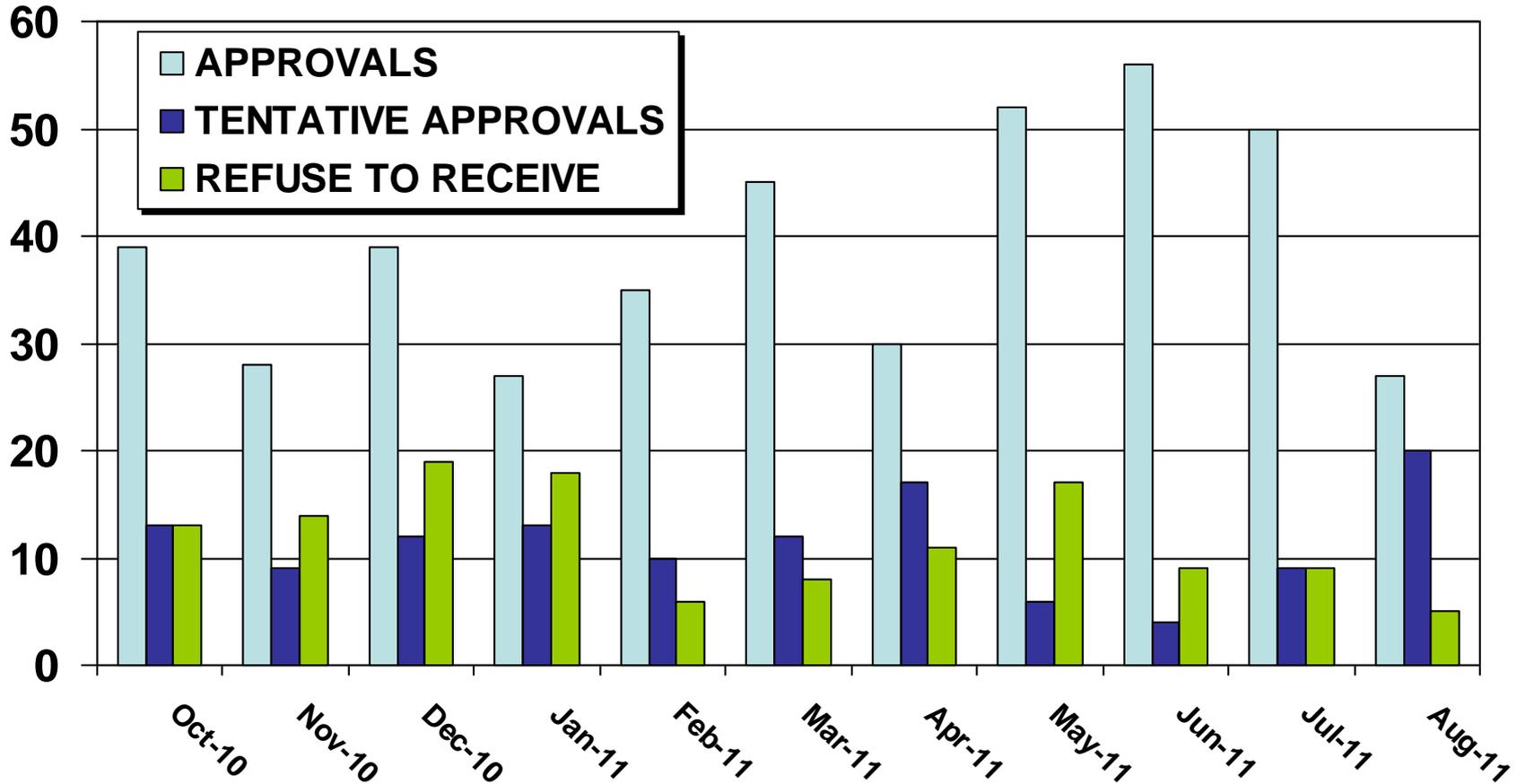
Total TAs = 136

ANDA Receipts



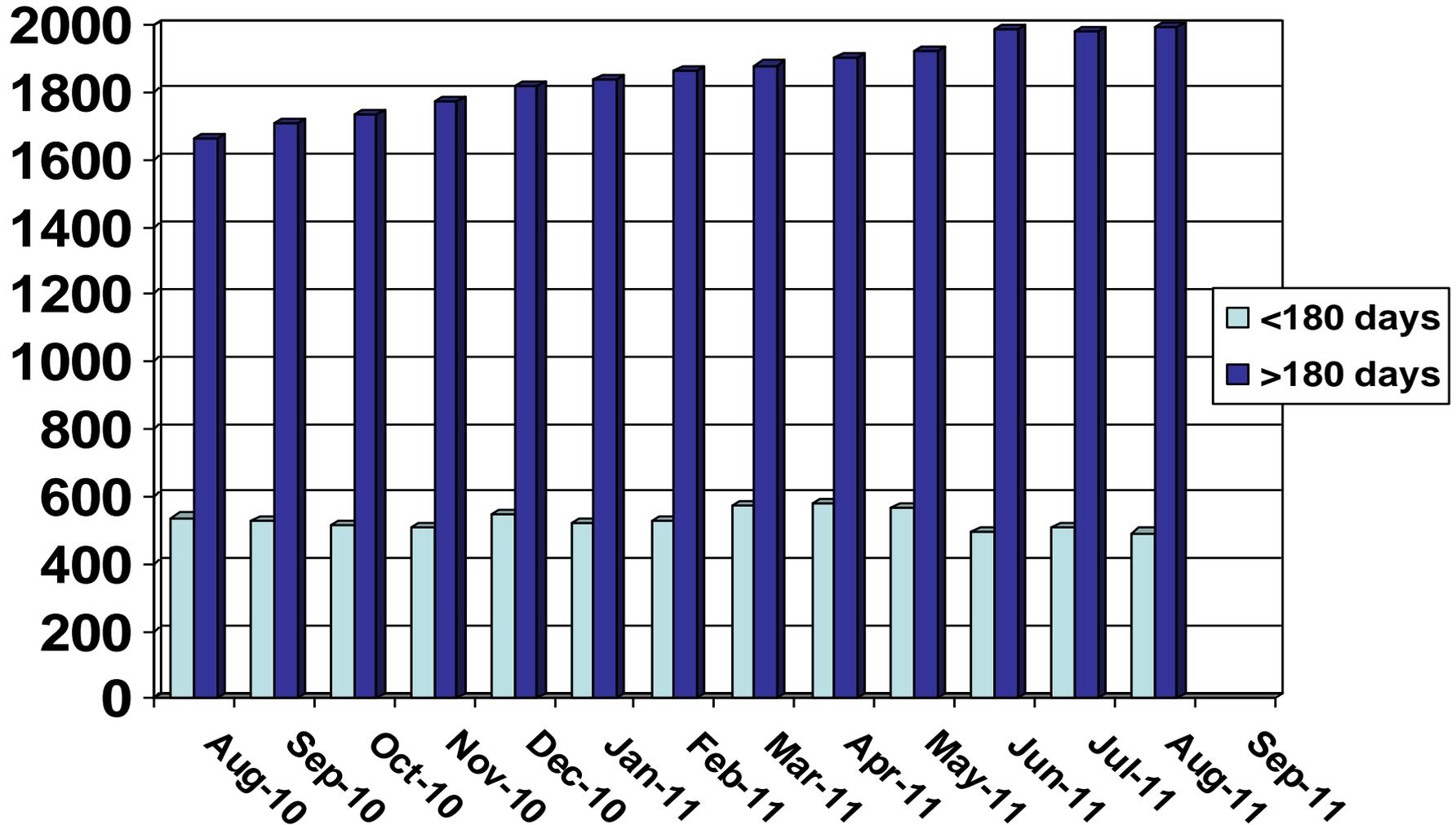


ANDAs



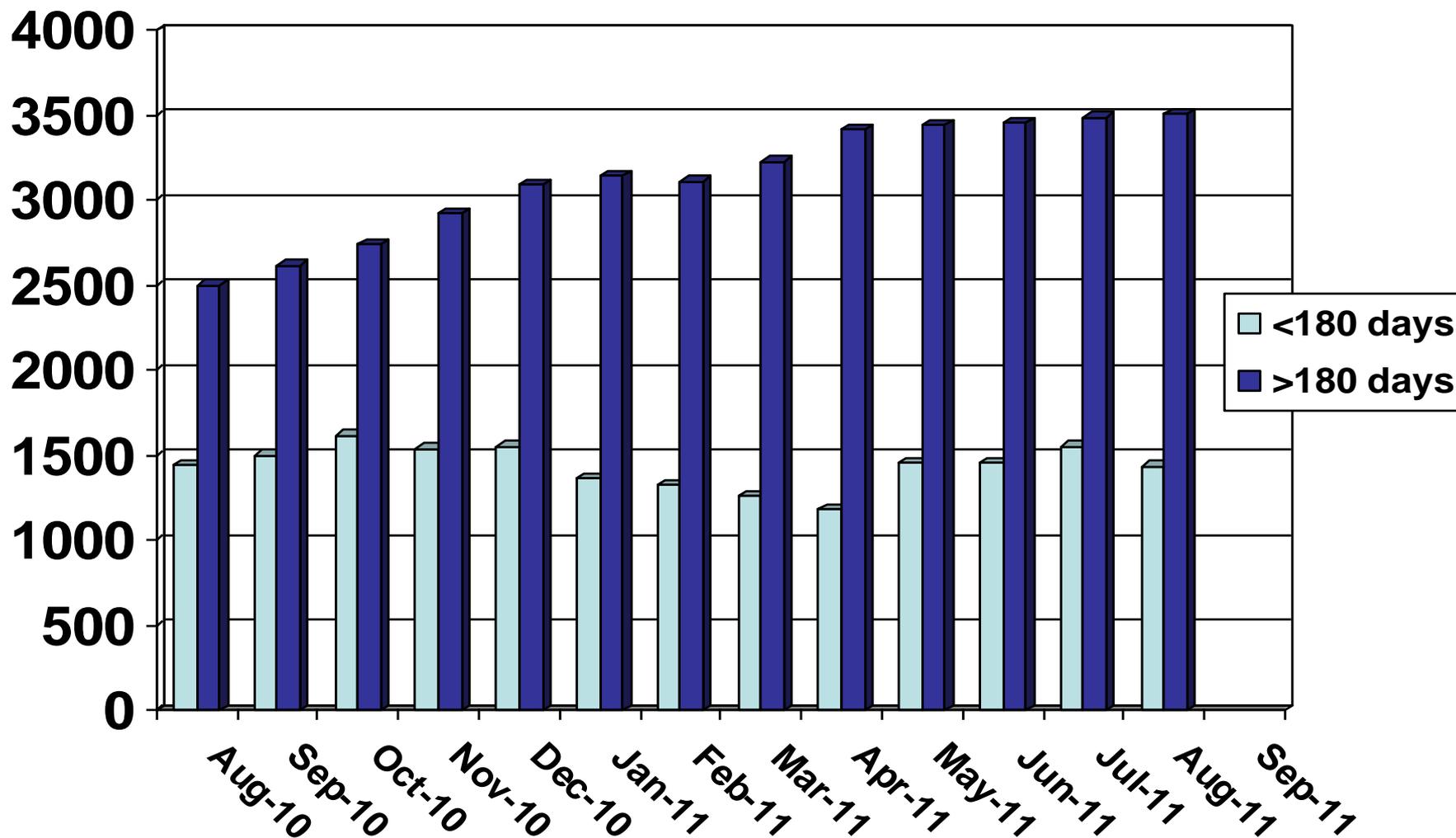


Pending ANDAs by Month





Pending CMC Suppls by Month





Accomplishments

- Implementation of QbD
- Moving ahead with the recommendations from the McKinsey Study
- Excellent progress on the Quality Management System
- Generic Drug User Fee Negotiations Finished



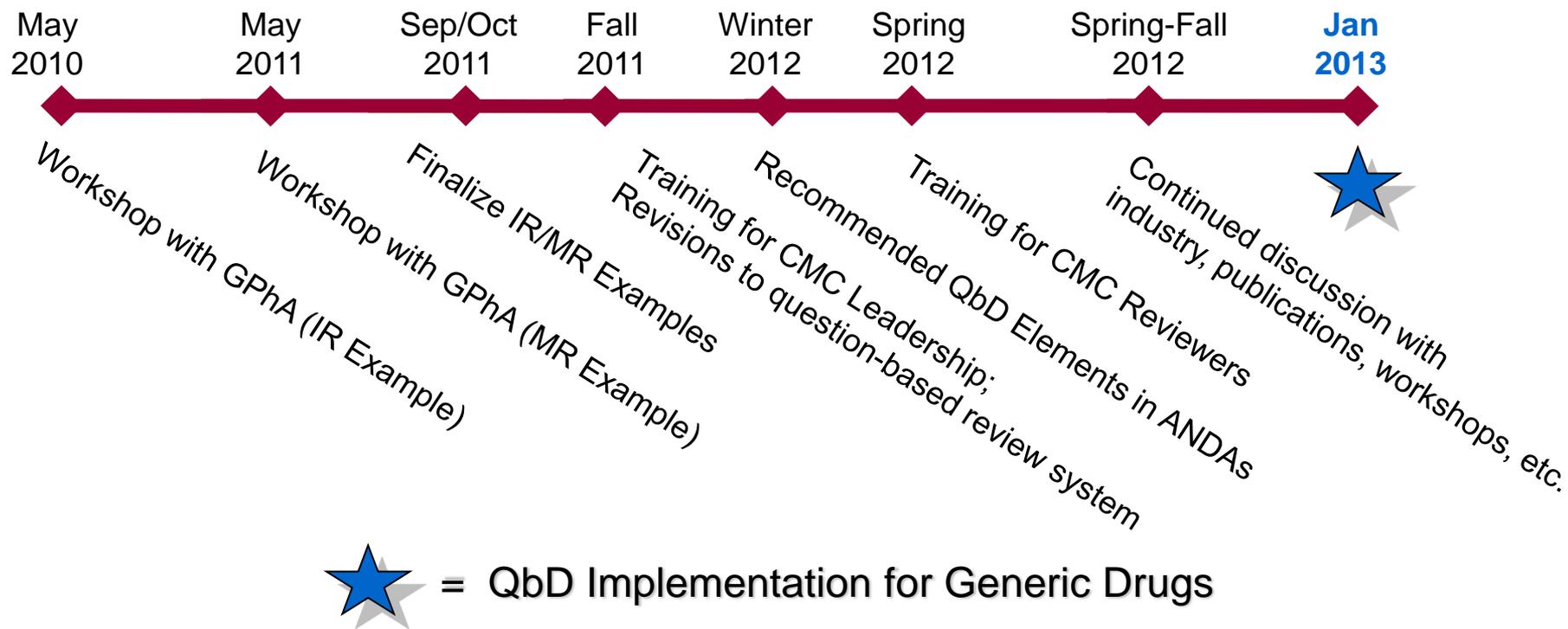
Quality-by-Design

Excellent Progress

- Immediate-Release SOD Example
- Modified-Release SOD Example
- Plans in-place for:
 - Revising Question-Based-Review system
 - Training review staff
 - Implementation Workshops with Industry



Timeline for QbD Implementation



Consultant Recommendations

- Tighten “Filing Criterion”
- Cross-discipline review teams
- Project Management of review teams
- Use “Dashboard” to track progress of ANDA reviews
- Separate API (DMF) review from DP review
- Utilize Complete Response letters



Tighter Filing Criteria

- 'Filing Requirements' checklist on website
- Ongoing re-assessment of list
- Quarterly revisions published on web

Cross-discipline teams

Project-management of teams

Implemented:

Chemistry Division-specific meetings

- Focus on ANDA review progress
- Cross disciplinary
- Chemistry PMs responsible for report-out

Implementing:

Review Flow System

- Tracks review progress in each discipline

Separate API (DMF) review from DP review

- DMF review team established in May 2011
- Focus on synthesis & quality requirements of API
- Will be crucial to DMF GDUFA goals
- Currently, eight reviewers, plus TL
- Will expand when additional resources come



Utilize Complete Response letters

- Have been used infrequently in OGD
- CR is a major GDUFA goal
- Plan to use CR, TA, AP letters for all ANDAs starting in January 2012
- Will balance 314.102 (early info requests) with 314.110 (CR letters)

Quality Management System

Components:

- Documentation of procedures
- Ensure that people know the processes and follow them.
- Audit conformance with processes
- Add & edit processes as needed



Generic User Fee

Major Points of Agreement

- Much needed additional resources across FDA
- Performance Goals for FDA
- Transition to a surveillance inspection system

Still needs review by DHHS, passage by Congress, signature by President Obama



GDUFA Goals

Review Goals and Metrics for:

- Pending ANDAs
- New ANDAs
- Drug Master Files
- Minor & Major Amendments
- Prior-Approval Supplements
- Controlled Correspondence



Implementation Committee

- Identify needed processes and process changes
- Are organizational changes needed?
- Coordinate implementation across FDA and within OGD



Needed within OGD

- Review Staff
- Support staff
- Quality Assurance Staff
- 'Direct-Hire' Authority
- Post-Approval Safety Monitoring
- Staff Training
- IT & Database support
- Knowledge management
- Regulatory research



Blockbusters Coming off Patent

Date	Drug
Oct. 2011	Zyprexa (olanzapine)
Nov. 2011	Lipitor (atorvastatin)
Mar. 2012	Lexapro (escitalopram)
	Seroquel (quetiapine)
	Avapro/Avalide (irbesartan)
Apr. 2012	Provigil (modafinil)
May 2012	Plavix (clopidogrel)
Aug. 2012	Singulair (montelukast)
	Actos (pioglitazone)
Sep. 2012	Diovan (valsartan)
	Geodon (ziprasidone)

Bold = TA'd



Questions?