Office of Generic Drugs (OGD) Director’s Update

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Director, Office of Generic Drug
CDER/FDA

GPhA Annual Meeting
February 23, 2016
Disclaimer

• This presentation reflects the views of the speaker and do not reflect official FDA, HHS, or other government opinion or policy.

• I have nothing to disclose.
OUTLINE

1. GDUFA update
2. Output & Productivity
3. Quality of ANDA Submissions
4. Update on Pre-Year 3 cohort
5. Opportunities for Improvement & Challenges

Common Problems seen in ANDAs
Ways for Industry to “Control your Destiny”
GDUFA IMPLEMENTATION

• Agency is meeting ALL of its obligations under GDUFA commitment letter
• We are going above and beyond the commitments
• Building a modern, 21st Century generic drug program
• Resulting in significant and sustained increase in communications, actions & approvals
GDUFA IMPLEMENTATION

• Productivity up: actions and APs/TAs
• Communications up: hundreds/month
• Pre Year 3 ANDAs:
  – TADs issued and communicated to industry
  – Formula for review timeframes
  – Workload knowledge
First QTR FY2016
(October, November, December 2015)

• Approvals - 190
• Tentative Approval (TA) - 48
• Complete Response (CR) – 310
• December 2016 – highest number of approvals/TA in one month EVER - 99

• In CY2015 – broke 700 AP + TA HIGHEST NUMBER EVER
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GDUFA
MAJOR PROGRAM GOALS
(5 year plan)

1. Metrics
   – Applications
   – GDUFA Backlog
   – cGMP Inspections

2. Efficiency enhancements

3. Regulatory science
GDUFA IMPLEMENTATION

Build the Machine

• Deep foundational restructuring
• Build infrastructure
• Improve business processes
• Hire and train new staff
• New IT platform
• Improve communications

• All to prepare for Year 3 Goal Dates AND to enable us to hit goal dates
GDUFA Hiring Progress

- Hires (Cumulative)
- GDUFA Target (Cumulative)

FY 13: 291
FY 14: 692
FY 15: 923

Total: 1192
IT IMPROVEMENTS

• Improved communication and increased productivity are the direct result of our improved IT system for the generic drug program
• Provides workload management & review management tools
• Enables prioritization process for 1st generics, PIVs, exclusivity type issues
• OVER 130,000 assignments in new Platform
CDER Informatics “Platform”

<table>
<thead>
<tr>
<th>New Capabilities &amp; Functions</th>
<th>Benefits to FDA &amp; Industry</th>
</tr>
</thead>
</table>
| **Integrated Data Management** | • Ensures synchronization of data across CDER to assure high data quality  
• Provides a single source of truth for application and submission data  
• Supports transition to more electronic submissions  

**Integrated Workflow Management** | • Supports faster review times (e.g. 25% improvement in FY15 approvals and tentative approvals year over year)  
• Makes it easier to collaborate and communicate with Industry  
• Improves review consistency by making it easier to study precedent applications  
• Makes ANDA review times and target completion dates more predictable  

**Analytics, Search and Reporting** | • Faster, more powerful search across all application types and documents  
• Dashboards and metrics to monitor progress and risk  
• Increased analytic capabilities to support data driven decision making |
SCOPE of IT IMPROVEMENTS

Improving Data Quality

Applications

1,086
New Originals Created
(ANDA-NDA-BLA-IND)

Facilities

39,521
Submission Linkages Created

25,877
Business operations created

Products

2,995
Products Created

23,724
Ingredients linked

Data Quality

13,206
Business Operations Updated

13,067
MDM IDs Updated

1,623
DUNS Updated

97
FEIs Updated

12,688/ Tasks Completed in Panorama

5,436/ Unique Panorama Projects Assigned

1,634/ Issues Resolved in Panorama
# GDUFA GOAL DATES

**Powerful tool to improve the timeliness and predictability of review**

<table>
<thead>
<tr>
<th>Goals</th>
<th>FY2015</th>
<th>FY2016</th>
<th>FY2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original ANDA</td>
<td>60% in 15 months</td>
<td>75% in 15 months</td>
<td>90% in 10 months</td>
</tr>
<tr>
<td>Tier 1 first major amendment</td>
<td>60% in 10 months</td>
<td>75% in 10 months</td>
<td>90% in 10 months</td>
</tr>
<tr>
<td>Tier 1 minor amendments (1st - 3rd)</td>
<td>60% in 3 months*</td>
<td>75% in 3 months*</td>
<td>90% in 3 months*</td>
</tr>
<tr>
<td>Tier 1 minor amendments (4th - 5th)</td>
<td>60% in 6 months*</td>
<td>75% in 6 months*</td>
<td>90% in 6 months*</td>
</tr>
<tr>
<td>Tier 2 amendment</td>
<td>60% in 12 months</td>
<td>75% in 12 months</td>
<td>90% in 12 months</td>
</tr>
<tr>
<td>Prior approval supplements</td>
<td>60% in 6 months*</td>
<td>75% in 6 months*</td>
<td>90% in 6 months*</td>
</tr>
<tr>
<td>ANDA teleconference requests</td>
<td>Close-out 200</td>
<td>Close-out 250</td>
<td>Close-out 300</td>
</tr>
<tr>
<td>Controlled correspondences</td>
<td>60% in four months*</td>
<td>70% in two months*</td>
<td>90% in two months*</td>
</tr>
</tbody>
</table>

ANDA, amendment and PAS in backlog on Oct 1, 2012

Act on 90% by end of FY 2017

*10 months if inspection required*

**Performance goals in the chart means FDA should take an action on a certain percent of applications, etc. within the timeframes listed; it does not mean FDA should approve applications, etc. within such timeframes.***
OGD & OPQ believe, in working with Industry, by Year 5 the 1st cycle approvability rate for ANDAs can be improved. This goal is achievable provided the ANDA submissions we receive are of high quality and complete upon first submission.
GDUFA

TRANSFORM THE PROGRAM

and

PERFORM WHILE TRANSFORM

We built the machine…

NOW we are cranking it up!
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   Common Problems seen in ANDAs
   Ways for Industry to “Control your Destiny”
OUTPUT & PRODUCTIVITY

INCOMING from INDUSTRY

OUTPUT from FDA

• GDUFA Backlog
• ANDAs
• PASs
• Filing
• Communication
• Controlled Correspondence
• Guidance
PROJECTED vs ACTUAL ANDA RECEIPTS

FDA Received
Approximately
5.5 Years of Projected
ANDA Receipts in 4 years

750 Projected
ANDAs per year

*Numbers are based on current data and will be further scrubbed for formal reporting purposes.
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CONTROLLED CORRESPONDENCE RECEIPTS

**Controlled Correspondences Received under GDUFA**
(by discipline) FY13 - FY15

*Numbers are based on current data and will be further scrubbed for formal reporting purposes*
## OVERALL ACTIONS

### PRE-GDUFA vs. GDUFA

<table>
<thead>
<tr>
<th></th>
<th>FY2012</th>
<th>FY2013</th>
<th>FY2014</th>
<th>FY2015*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANDA approvals</strong></td>
<td>517</td>
<td>440</td>
<td>409</td>
<td>490</td>
</tr>
<tr>
<td><strong>Tentative Approval (TA)</strong></td>
<td>102</td>
<td>95</td>
<td>91</td>
<td>120</td>
</tr>
<tr>
<td><strong>PAS approvals</strong></td>
<td>275</td>
<td>535</td>
<td>659</td>
<td>624</td>
</tr>
<tr>
<td><strong>Complete Response (CR)</strong></td>
<td>84</td>
<td>1251</td>
<td>1254</td>
<td>1007</td>
</tr>
<tr>
<td>**TOTAL **</td>
<td>978</td>
<td>2226</td>
<td>2413</td>
<td>2241</td>
</tr>
<tr>
<td><strong>DMF Completeness Assessment (CA)</strong></td>
<td>0</td>
<td>1699</td>
<td>1706</td>
<td>901</td>
</tr>
</tbody>
</table>

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** FDA will aspire to the extent possible to maintain levels of productivity at least similar to pre-GDUFA levels, while hiring and training incremental staff necessary to achieve the program performance goals, building necessary systems and implementing outlined program changes in years 1 and 2 of the program (GDUFA Commitment Letter, page 3).
** FDA will aspire to the extent possible to maintain levels of productivity at least similar to pre-GDUFA levels, while hiring and training incremental staff necessary to achieve the program performance goals, building necessary systems and implementing outlined program changes in years 1 and 2 of the program (GDUFA Commitment Letter, page 3)

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APPROVALS AND TENTATIVE APPROVALS
FY2014, FY2015 & 1st QTR FY2016
(GDUFA YEARS 2, 3, 1st QTR 4)

*Numbers are based on current data and will be further scrubbed for formal reporting purposes
## Significant First Generic Approvals for 2015

<table>
<thead>
<tr>
<th>Brand (Generic name)</th>
<th>Indications (Abbreviated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abilify® (aripiprazole)</td>
<td>Schizophrenia, Bipolar Disorder</td>
</tr>
<tr>
<td>Copaxone ® (glatiramer)</td>
<td>Multiple sclerosis</td>
</tr>
<tr>
<td>Enablex® (darifenacin)</td>
<td>Overactive bladder</td>
</tr>
<tr>
<td>Fusilev® (levoleucovorin)</td>
<td>Supports cancer treatment</td>
</tr>
<tr>
<td>Lotronex® (alosetron)</td>
<td>Irritable bowel syndrome</td>
</tr>
<tr>
<td>Integrelin® (eptifibatide)</td>
<td>Heart attack</td>
</tr>
<tr>
<td>Norvir ® (ritonavir)</td>
<td>HIV-1 infection</td>
</tr>
<tr>
<td>Orap ® (pimozide)</td>
<td>Tourette’s Disorder</td>
</tr>
<tr>
<td>Transderm Scop® (scopolamine)</td>
<td>Motion sickness</td>
</tr>
<tr>
<td>Tygacil® (tigecycline)</td>
<td>Pneumonia, serious infections</td>
</tr>
<tr>
<td>Vagifem® (estradiol)</td>
<td>Menopause</td>
</tr>
<tr>
<td>Xenazine® (tetrabenazine)</td>
<td>Huntington’s Disease</td>
</tr>
<tr>
<td>Zyvox® (linezolid)</td>
<td>Pneumonia, serious infections</td>
</tr>
</tbody>
</table>
### GDUFA Backlog Applications with First Action through 12/31/15

<table>
<thead>
<tr>
<th>Actions</th>
<th>ANDAs</th>
<th>PAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number with First Action**</td>
<td>2414</td>
<td>1666</td>
</tr>
<tr>
<td>Percentage Complete</td>
<td><strong>84%</strong></td>
<td><strong>88%</strong></td>
</tr>
<tr>
<td>Approval</td>
<td>609</td>
<td>959</td>
</tr>
<tr>
<td>Tentative Approval</td>
<td>151</td>
<td>4</td>
</tr>
<tr>
<td>Complete Response with Inspection*</td>
<td>1384</td>
<td>465</td>
</tr>
<tr>
<td>Refuse to Receive</td>
<td>69</td>
<td>2</td>
</tr>
<tr>
<td>Withdrawn Applications</td>
<td>201</td>
<td>236</td>
</tr>
</tbody>
</table>

**Complete Response with an Inspection is a written FDA communication to an applicant usually describing all of the deficiencies that the agency has identified in an application that must be satisfactorily addressed before it can be approved.

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**GDUFA BACKLOG:**
2866 original ANDAs
1873 PAS supplements

**GDUFA GOAL:**
90% get first ACTION by end of GDUFA YR 5 (9/30/2017)
*Numbers are based on current data and will be further scrubbed for formal reporting purposes.

*Goal dates provided through February 2015, as those are the goal dates that have actually accrued. The cohort data is not mature enough to report on whole year data.

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Eliminating ANDA Filing Backlog

Total Backlog of ANDAs

- Sep-14: 1137
- Oct-14: 1017
- Nov-14: 957
- Dec-14: 830
- Jan-15: 712
- Feb-15: 634
- Mar-15: 565
- Apr-15: 526
- May-15: 471
- Jun-15: 426
- Jul-15: 340
- Aug-15: 277
- Sep-15: 177
- Oct-15: 8
- Nov-15: 8
- Dec-15: 2
FILING REVIEW

• There is **NO** filing backlog
  – Pre-year 3 applications: Done!
  – Reviewed, filed, or RTRRed
  – FY 2015 >1,500 filing reviews completed

• Filing being done in real time
  – Current: 31 days
FILING

• First step in REVIEW
• Acceptable for FILING means that the application is sufficiently complete to permit substantive review
• It does not mean that application will be approved
• 1st inning home run vs. winning the ball game
PRODUCTIVITY
COMMUNICATION WITH INDUSTRY
EASILY CORRECTABLE DEFICIENCIES (ECDs) & INFORMATION REQUESTS (IRs)

OVER 4,700 communications to industry last FY during ANDA review

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PRODUCTIVITY

ANDA Complete Response (CRs)

*Numbers are based on current data and will be further scrubbed for formal reporting purposes
Exceeding Controlled Correspondence Goals

FY15 GDUFA Performance by FDA Receipt Date - All Disciplines

**Numbers are based on current data and will be further scrubbed for formal reporting purposes.**
Eliminated Controlled Correspondence Backlog

Workload Summary Pre-FY15
GDUFA Controls (submitted prior to 10/2014)

** Numbers are based on current data and will be further scrubbed for formal reporting purposes.
Product-Specific ANDA Guidances
Notable FY2015 Product Specific Guidances

- Recommendations on more complex dosage forms
  - 2 inhalation powders, 3 MDI, 4 nasal sprays
  - 1 buccal tablet, 1 sublingual spray, 1 dental powder, 1 buccal film
  - 8 ophthalmic solutions or suspensions
  - 9 topical semi-solids, 3 topical spray/foam
  - 3 transdermal systems, 1 otic suspension, 2 ER injections
Notable FY2015 Guidances (cont)

• **Conjugated Estrogen**
  - Complex mixture with no previous ANDA pathway
  - FDA lab work on analytical methods
  - Significant work across CDER

• **Size & Shape Guidance (OGD + OPQ)**
  - Draft published 6/18/2015
  - This guidance is not being used for Filing decisions
  - Useful for industry to understand what FDA is looking for/at during scientific and clinical review
Orange Book Express Mobile App

- Search the public Orange Book Database for Approved Drugs and Patent and Exclusivity Information
- Search all marketing statuses (Rx, OTC, Discontinued) with one search
- Identify Reference Listed Drugs (RLDs) and determine if a drug product is considered to be a therapeutic equivalent
- Browse Patent Delistings and Newly Added Patents
- Launched 11/9/2015, 18K+ downloads
- Available for Android and iOS devices
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METRICS for Application Quality

1. RTR
2. 1st cycle approval
3. Number of review cycles
## FILING – Refuse to Receive (RTR)
*(Based on cohort year of submission)*

<table>
<thead>
<tr>
<th>YEAR</th>
<th># RTR’s</th>
<th>% of Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY2010</td>
<td>146</td>
<td>18%</td>
</tr>
<tr>
<td>FY2011</td>
<td>142</td>
<td>16%</td>
</tr>
<tr>
<td>FY2012</td>
<td>156</td>
<td>14%</td>
</tr>
<tr>
<td>FY2013</td>
<td>193</td>
<td>19%</td>
</tr>
<tr>
<td>FY2014</td>
<td>191</td>
<td>13%</td>
</tr>
<tr>
<td>FY2015</td>
<td>124</td>
<td>23%</td>
</tr>
</tbody>
</table>

Compared with first years of PDUFA: 10-30% Refuse to File (RTF)

*Numbers are based on current data and will be further scrubbed for formal reporting purposes*
YEAR 3 Applications

• Submitted October 2014
• GDUFA GOAL DATES – January 2016
# Year 3 APPROVALS/TA

*Through 1/31/16 (15 month goal)*

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>ANDA Number</th>
<th>Company</th>
<th>Date of Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tretinoin</td>
<td>207955</td>
<td>Spear</td>
<td>08/13/2015</td>
</tr>
<tr>
<td>Loperamide*</td>
<td>206548</td>
<td>Aurobindo</td>
<td>12/15/2015</td>
</tr>
<tr>
<td>Gabapentin</td>
<td>206402</td>
<td>Alkem</td>
<td>12/23/2015</td>
</tr>
<tr>
<td><strong>Active Ingredient</strong></td>
<td><strong>ANDA Number</strong></td>
<td><strong>Company</strong></td>
<td><strong>Date of Tentative Approval</strong></td>
</tr>
<tr>
<td>Diclofenac</td>
<td>208068</td>
<td>Paddock</td>
<td>10/14/2015</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>208098</td>
<td>Taro</td>
<td>01/14/2016</td>
</tr>
<tr>
<td>Sildenafil*</td>
<td>206401</td>
<td>Ajanta</td>
<td>01/21/2016</td>
</tr>
<tr>
<td>Lurasidone</td>
<td>208037</td>
<td>MSN Labs</td>
<td>01/25/2016</td>
</tr>
<tr>
<td>Lurasidone</td>
<td>208031</td>
<td>Lupin</td>
<td>01/25/2016</td>
</tr>
<tr>
<td>Lurasidone</td>
<td>208066</td>
<td>Sun Pharma</td>
<td>01/25/2016</td>
</tr>
<tr>
<td>Risedronate</td>
<td>205280</td>
<td>Orchid</td>
<td>01/29/2016</td>
</tr>
</tbody>
</table>

AP or TA issued on or before GDUFA goal date

*Not a first cycle AP/TA*

Information available at: Drugs@FDA website:
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm
Oct 2014 Submission Status (51 Submissions)
As of 1/31/16, GDUFA GOAL DATE in January 2016*

- Approved, 2
- Complete Response, 38
- Pending, 3
- Refuse-to-Receive, 4
- Tentative Approval, 4

12% first cycle approval rate
75% complete response
(will need another review cycle)
>90% met GDUFA goals

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CMC Review Cycles for ANDAs to Approval

2009 through July 2014

Number of Approvals

Cycle Number

Moving Average Trendline
First Cycle Approval Rate Under PDUFA

CDER NME NDAs/BLAs†
First Action Approval Rate

Fiscal Year of Receipt

First Cycle Approvals

<table>
<thead>
<tr>
<th>Year</th>
<th>First Cycle Approvals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>36%</td>
</tr>
<tr>
<td>1994</td>
<td>23%</td>
</tr>
<tr>
<td>1995</td>
<td>30%</td>
</tr>
<tr>
<td>1996</td>
<td>50%</td>
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<td>1998</td>
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<td>1999</td>
<td>54%</td>
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<td>2000</td>
<td>31%</td>
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<td>25%</td>
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<td>2002</td>
<td>50%</td>
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<td>2003</td>
<td>48%</td>
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<td>2004</td>
<td>42%</td>
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<td>2005</td>
<td>45%</td>
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<td>2006</td>
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<td>52%</td>
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<td>2008</td>
<td>46%</td>
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<td>2009</td>
<td>43%</td>
</tr>
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<td>2010</td>
<td>56%</td>
</tr>
<tr>
<td>2011</td>
<td>70%</td>
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<tr>
<td>2012</td>
<td>72%</td>
</tr>
<tr>
<td>2013</td>
<td>78%</td>
</tr>
<tr>
<td>2014</td>
<td>89%</td>
</tr>
<tr>
<td>2015*</td>
<td>95%</td>
</tr>
</tbody>
</table>
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## GENERIC DRUG REVIEW DASHBOARD

### Pre-Year 3 ANDAs

- **LAUNCHED 2/5/16**

### FDA Snapshot

- 6 Pending Filing Review
- 426 Filed - No Review Comm.
- 1,928 At Least One Review Communication Issued
- 2,360 with FDA

### Monthly Average

- (Sept - Dec)
- Complete Response 94
- Amendments 84
- 414 Info. Req. 441
- Tentative Approvals 14

### Industry Snapshot

- 843 Pending Industry Response
- 267 Tentative Approval with Industry
- 1,110 with Industry

### Current ANDA Workload of Original Applications

- 3,470

### Total Pre-Y3 Application Cohort

- 1,496 Approvals
- Refuse to Receive 80 Resubmitted in Y3
- 491 Withdrawals (from Cohort)
- 3,470

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*Numbers are based on current data and will be further scrubbed for formal reporting purposes*

[Source](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm484609.htm)
ALL ANDA “active” WORKLOAD
(n=6218; FDA Testimony to Senate HELP Committee, 1/28/16)

Includes Pre-GDUFA (“backlog”) & GDUFA ANDAs accepted for filing only; approximate workload.
*Numbers are based on current data and will be further scrubbed for formal reporting purposes
COMMUNICATIONS ENHANCEMENTS FOR PRE-YEAR 3 ANDAs

- Complete Responses pending inspections
- Information Requests (IRs), Easily Correctible Deficiencies (ECDs) and Real Time Communication
- Target Action Dates (TADs) assigned & communicated to industry
  - TLC for 1st generics to align with patent or exclusivity expiration
- Other launch planning communications related to TADs
- Updated Communications with Industry MAPP to formalize and clarify these changes for pre-Year 3 applications
## PREDICTABILITY for INDUSTRY

TADs for Additional Cycles (Pre-Year 3)

<table>
<thead>
<tr>
<th>Category</th>
<th>Pre-cohort Year 3 ANDAs</th>
<th>Pre-cohort Year 3 ANDAs (expedited status)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major (CR)</td>
<td>10 months</td>
<td>7 months</td>
</tr>
<tr>
<td>Minor (CR)</td>
<td>5 months</td>
<td>3 months</td>
</tr>
<tr>
<td>ECD</td>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td>IR</td>
<td>3 months</td>
<td></td>
</tr>
</tbody>
</table>
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   Common Problems seen in ANDAs
   Ways for Industry to “Control your Destiny”
“How an ANDA Gets Approved”

Presentation at GPhA Fall Tech  
November 3, 2015  
Speakers: Kevin Denny, (OGD)  
Craig Kiester (OPQ)

Presentation: 1.5 hours long, 109 slides
• Use the right form
• Complete the form entirely
• If foreign, must use a US agent
• Pay appropriate fees

• Point of Contact: one person vs. general company email and phone number (e.g., regaffairs@genericcompanyx.com)
OPPORTUNITIES & CHALLENGES

• Use Cover Letter with **every** submission
  – Identify content of submission
    • IR response
    • BE studies
    • New facilities
OPPORTUNITIES & CHALLENGES

IR responses:
– Please respond to ONLY those issues raised by FDA in IR
– Please do not include:
  • Lots of extraneous information over what was requested
  • Tons of data, 1,000s of pages of reports
  • Information that is off topic
  • Other discipline
  • New facility
OPPORTUNITIES & CHALLENGES

Facilities:

• Need to use 356h form
• New facilities in submission without flagging this to Agency
• Facilities added in IR response – out of scope
• New facilities added at end of review cycle
OPPORTUNITIES & CHALLENGES

• Need for **litigation updates** as you are nearing GDUFA goal date or TAD

• Failure to provide **Patent updates**

• Submit these to **ANDA**
  – not to me or the RPM
OPPORTUNITIES & CHALLENGES

• Stay on top of:
  – RLD labeling changes
  – REMS modifications

• IF there are changes to either of these, ANDA applicant needs to submit revised labeling or REMS
CONCLUSIONS
YEAR 3 METRIC GOALS
How are we doing?

• **GDUFA Backlog** – FDA is way ahead of schedule – 86+% have received 1\textsuperscript{st} action
• **PASs** – FDA is exceeding goals
• **Controls** – FDA is exceeding goals
YEAR 3 METRIC GOALS
How are we doing?

• **ANDAs** – too soon to tell; we are confident
• **Amendments** – too soon to tell; we are confident

• **Quality of Submissions** – too soon to tell
WHAT IS NEXT?

Years 4 & 5:

- Review metrics tighten
- There will be up months and down months, but overall productivity on pre-Year 3 submissions will continue to increase

Strong focus on:

- TADs and related communications
- *First generics*: Avoid FTF PIV forfeitures, pursue timely first generic approvals
WORKING TOGETHER

- FDA and Industry continue to work together to ensure ultimate aims of GDUFA --- Safety, Access and Transparency -- are achieved
- Success of program is the direct result of intensive Agency-Industry collaboration
- We appreciate the open and honest dialogue to evaluate challenges and develop impactful improvements
REAPING THE BENEFITS

• FDA is fulfilling its GDUFA commitments

• In many cases, we are going above and beyond our negotiated commitments

• We are building a robust, modern generic drug regulatory program
  – Sustainable and predictable
  – Clear and consistent communication
  – Fairness across applications and applicants
GDUFA…..
Not only “Can” we do it…..we ARE DOING IT

FDA and Industry are working together to provide affordable, high quality generic medications for the American public
THANK YOU!