Product Launch Preparation

Project Manager Exposition
2015 GPHA Fall Technical Conference

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Why?

- Generic products saved the U.S. healthcare system nearly $1.5 trillion over the 10 year span of 2004-2013\(^1\)

- Generic pharmaceuticals saved federal and state programs, consumers, taxpayers, businesses, and others $239 billion in 2013 alone\(^1\)

\(^1\) GPHA Generic Drug Savings in The U.S.; Sixth Annual Edition; 2014
Consumer Impact:

- Earliest possible access to high quality affordable healthcare products
- On average, the cost of a generic drug is 80 to 85 percent lower than the brand name product.²

² Facts About Generic Drugs; FDA website; June 19, 2015
Risks Impacting Launch Preparation:

- Unexpected protracted review duration
  - Toxicology consult, etc.

- Late in review process:
  - Request to change conditions of approval
  - Request to change labeling content
  - RLD labeling change approval
  - Late listed patent(s)
  - Site inspection request
  - PLAIR issues or Customs holds
  - DMF changes
Risks Managed by Sponsor

• $50k - $1 million per batch
  – Manufacturing multiple batches
    • Validation batches
    • Launch batches
  – Costs include:
    • API
    • Pkg/Labeling components
    • Labor, etc.
Complexity Impact

- Can significantly impact launch preparation action plan
  - Multiple strengths or flavors
  - Multiple presentations (ex: adult and children labels)
  - Mfg processes
  - Conflicts with normal production schedule
  - Dosage forms
  - Contract mfg sites
  - OUS Suppliers
  - PLAIR
  - ROW impact (holidays, extended vacations, etc.)
## Typical “At Risk” Pre-Launch Activities & Timing

<table>
<thead>
<tr>
<th>Activities</th>
<th>Timing (out from approval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validation batches</td>
<td>2 – 6 months</td>
</tr>
<tr>
<td>– Process, Product, Packaging</td>
<td></td>
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<tr>
<td>Mfg Launch Quantities</td>
<td>0 – 4 months</td>
</tr>
<tr>
<td>Child-Resistant Testing</td>
<td>2 – 6 months</td>
</tr>
<tr>
<td>Obtain DEA quotas</td>
<td>8 – 12 weeks</td>
</tr>
<tr>
<td>Shipping tests</td>
<td>1 – 2 months</td>
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<tr>
<td>Customs issues (PLAIR)</td>
<td>1 - 2 months</td>
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<tr>
<td>– Entry delays</td>
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<tbody>
<tr>
<td>• Art Development/Approval</td>
<td>4 – 20 weeks</td>
</tr>
<tr>
<td>• Order Labeling &amp; Pkg. Components</td>
<td></td>
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<tr>
<td>– Container labels</td>
<td>6 weeks</td>
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<tr>
<td>– Outer cartons</td>
<td>6 weeks</td>
</tr>
<tr>
<td>– Inserts/booklets/CDs</td>
<td>6 weeks</td>
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<tr>
<td>– Pre-printed tubes &amp; canisters</td>
<td>4 months</td>
</tr>
<tr>
<td>– Pre-molded plastics</td>
<td>2 – 6 months</td>
</tr>
<tr>
<td>– Foil pouches</td>
<td>3 – 6 months</td>
</tr>
<tr>
<td>– Printed bags</td>
<td>2 – 6 months</td>
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<tr>
<td>– Pre-assembled delivery devices</td>
<td>2 – 6 months</td>
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<tr>
<td><strong>Promotional Materials</strong>&lt;sup&gt;*&lt;/sup&gt;</td>
<td>4 months</td>
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<tr>
<td>– In-store displays</td>
<td></td>
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<tr>
<td>– Retailer</td>
<td></td>
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<tr>
<td>– Pharmacist</td>
<td></td>
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<tr>
<td>– Physician</td>
<td></td>
</tr>
<tr>
<td>– Required Submissions</td>
<td></td>
</tr>
<tr>
<td><strong>Secure Pharmacy Sourcing Accounts</strong></td>
<td>6 months</td>
</tr>
</tbody>
</table>

* Can represent significant investment but helps assure pharmacist/physician awareness of and patient/consumer compliance with dosing and labeling content.
GDUFA I:

FY 2016 Goal: 75% of ANDAs reviewed in 15 months

FY 2017 Goal: 90% of ANDAs reviewed in 10 months
GDUFA I: Year 5 Projection

Submission to Approval Duration: 30 months

- 30 month duration includes:
  - FDA time to review and issue ECDs, IRs, and CRLs
  - Sponsor time to respond to each FDA request
  - FDA time to review and close out sponsor response
Old World:
• Current Review duration = 42 – 44 months
• Less certainty
• Manage risk over longer time frame; staged approach using review status as guide

Submission to Approval Duration: 42-44 months
Includes FDA ECDs, IRS, CRLS and sponsor responses
Parallel path for sponsor preparation for Day 1 Launch
MISSION: LAUNCH DAY OF APPROVAL

New World:
• Future Review Duration = 30 months and less over time
• Greater certainty
• As review timelines are reduced, risks condensed into shorter time frame
• Plan ahead to ensure Consumer benefit Day 1

Submission to Approval Duration: 30 months or less
Includes FDA ECDs, IRS, CRLS and sponsor responses
Parallel path for sponsor preparation for Day 1 Launch
Acknowledgement of Contributors:

- Richard Stec
- Erin Bonovetz
- Jim Vander Roest
- Steve Leegwater