



FDA/GPhA Quarterly Board Meeting on GDUFA Implementation

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U.S. Food and Drug Administration***

February 26, 2014



Meeting Agenda

- | | |
|--|------|
| I. Introductions | All |
| II. Old Business/Action Item Follow Up From Last Meeting: | |
| A. GPhA Ask to FDA | FDA |
| 1) Easily Correctable Deficiencies (ECD) | |
| 2) Major/Minor Amendments | |
| 3) Pre-CR Major Deficiencies Prior to Complete Response | |
| 4) Discipline Specific Deficiencies | |
| B. Prioritizing ANDA PIV First to File | FDA |
| C. Proposal for Prioritizing Review of Unapproved ANDAs | GPhA |
| D. GDUFA Industry Responsibilities | GPhA |



Meeting Agenda *(continued)*

III. New Business:

- | | |
|----------------------------------|-----|
| A. Program Alignment Group (PAG) | FDA |
| B. OGD Policy Update | FDA |
| C. GDUFA Update | FDA |
| D. OGD Activities Report Update | FDA |

IV. Wrap-up and Next Steps

All



Introductions



PAG

FDA: Program Alignment Group (PAG)

Howard Sklamberg



U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

Old Business



FDA: GPhA Ask to Agency

- ECDs
- Major/Minor Amendments
- Pre CR Major Deficiencies



Easily Correctable Deficiency Progress

Issued ECDs 10/1/2013- 1/31/2014

| As of 1/31/2014: | |
|-------------------------|------------|
| | Total |
| Quality | 142 |
| Labeling | 78 |
| Bioequivalence | 26 |
| Microbiology | 22 |
| Clinical Bioequivalence | 3 |
| Dissolution | 9 |
| TOTAL | 280 |

- 156 confirmed ECD responses received & correctly coded
- >20 failed to respond in 10 business days - more than 3-5 days overdue
- 124 closed by mechanism other than ECD



Sample ECD Fax Communication to Industry

EASILY CORRECTABLE DEFICIENCY FAX

ANDA 123456

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North VII
7620 Standish Place
Rockville, Maryland 20855



APPLICANT: ABC Drugs, Inc.

TEL: 123-456-7890

ATTN: President, ABC Drugs, Inc.

FAX: 123-456-7899

FROM: Linda Park

FDA CONTACT PHONE: (240) 276-8536

Dear Sir:

This communication is in reference to your abbreviated new drug application (ANDA) dated January 1, 2014, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for ABC Capsules, 10 mg.

The deficiencies presented below represent *EASILY CORRECTABLE DEFICIENCIES* identified during the review and the current review cycle will remain open. You should provide a complete response to these deficiencies within ten (10) U.S. business days.

Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission:

EASILY CORRECTABLE DEFICIENCY
CHEMISTRY / BIOEQUIVALENCE / DISSOLUTION / CLINICAL / MICROBIOLOGY
LABELING

If you do not submit a complete response within ten (10) U.S. business days, the review will be closed and the listed deficiencies will be incorporated in the next COMPLETE RESPONSE. Please provide your response after that complete response communication is received along with your response to any other issued comments.

If you are unable to submit a complete response within ten (10) U.S. business days, please contact the Regulatory Project Manager immediately so a complete response may be issued if appropriate.

Please submit official archival copies of your response to the ANDA, facsimile or e-mail responses will not be accepted. A partial response to this communication will not be processed as an amendment and will not start a review.

If you have questions regarding these deficiencies please contact the Regulatory Project Manager, Linda Park at



Instructions for Industry to Respond to ECD

Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission:

EASILY CORRECTABLE DEFICIENCY

CHEMISTRY / BIOEQUIVALENCE / DISSOLUTION / CLINICAL / MICROBIOLOGY / LABELING

If you do not submit a complete response within ten (10) U.S. business days, the review will be closed and the listed deficiencies will be incorporated in the next COMPLETE RESPONSE. Please provide your response after that complete response communication is received along with your response to any other issued comments.

If you are unable to submit a complete response within ten (10) U.S. business days, please contact the Regulatory Project Manager immediately so a complete response may be issued if appropriate.

- Applicant must provide a complete and satisfactory response submitted to the ANDA within 10 U.S. business days of the request
- Applicant responds so that the reviewer may complete review
- Goal is to lead to action in a predictable timeframe



Example: ECD Amendment Cover Letter Page

February 21, 2014

Office of Generic Drugs
Food and Drug Administration
Document Room, Metro Park North VII
7620 Standish Place
Rockville, MD 20855

**Re: Easily Correctable Deficiency
Labeling**

**ANDA 123456
ABC Capsules, 10 mg**

** if Industry follows this example then ECD response will be coded correctly**



FDA: GPhA Ask to Agency

- Discipline Specific Deficiencies



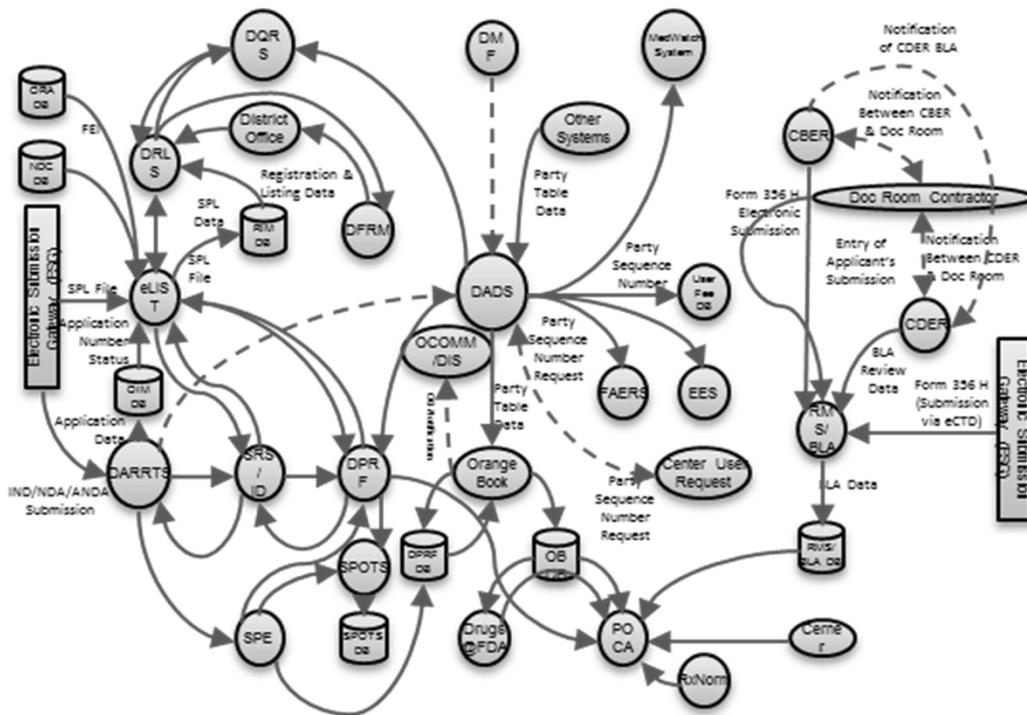
IT Current State: PROBLEMS

Individual Data Repository

Individual System Analytics

Multiple Reporting Methods

Major Challenges



Inconsistent Terminologies

Not User Friendly

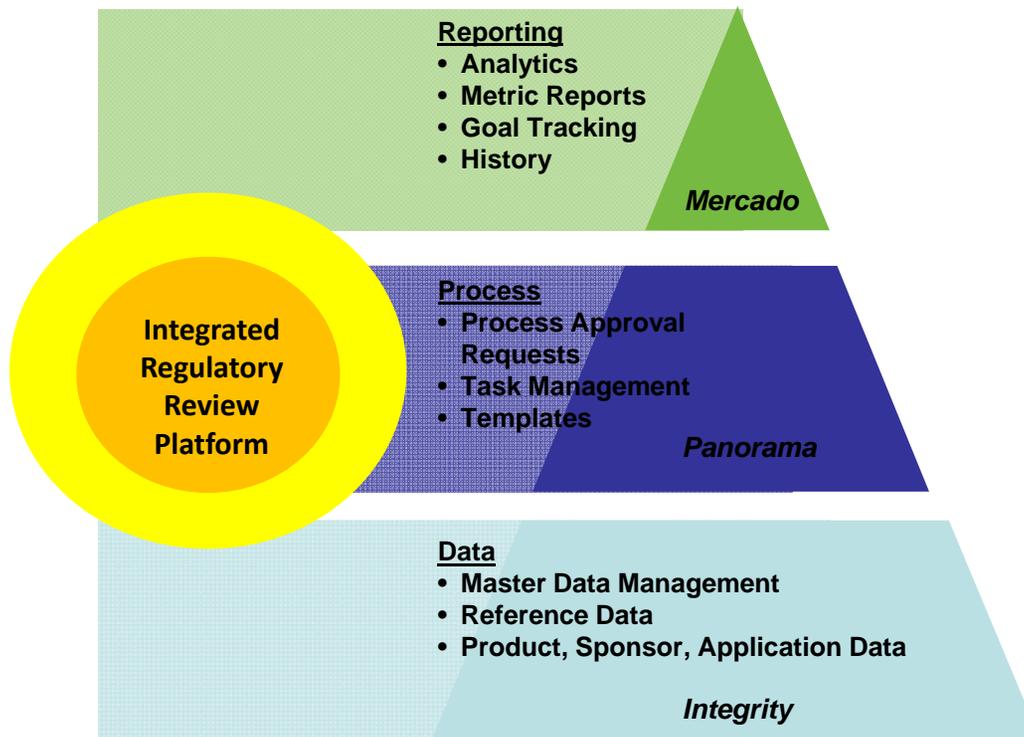
Not Flexible

Fragmented Data Sources



IT Future State: Enhanced IT Systems & Technology

“Getting to 2017”



Value to OGD:

- The ability to measure progress against goal dates
- Real-time visibility into queue and status of applications and reviews
- End-to-end support of the generic drug application review process
- Reduction of manual and/or duplicate entry
- Integrated searchable data, dynamic integrated reporting
- Visibility patent and exclusivity status, site inspection history, and standardized communications documents

Value to the Organization:

- Improved planning and forecasting
- Consistent data and consistent communication
- Structured reporting tools
- Greater predictability and transparency of the generic drug review process
- More efficient service to the public
- Integration of process and technology



FDA: Prioritizing PIV First to File ANDAs

| | Total as of 2/5/2014 |
|--|----------------------|
| Original ANDAs Pending OGD | 2921 |
| Original ANDAs Pending Firm | 718 |
| Originals - with Expedite Flag Included in Above | |
| GDUFA Year 1 & 2 PIV Expedites | 110 |
| GDUFA Backlog PIV Expedites | 85 |

- For GDUFA Year 1-2 submissions, per Commitment Letter, “FDA will strive to review and act on all ANDAs that are submitted on the first day that any valid Paragraph IV application for the drug in question is submitted... in order to avoid causing first applicants to inadvertently forfeit 180-day exclusivity...”
- For GDUFA backlog submissions, OGD is expediting review of first filer PIVs, despite the absence of a GDUFA commitment, because they are public health priorities.
- Above numbers exclude ANDAs that OGD already has acted on.



GPhA: Proposal for Priority Review of Unapproved ANDAs

- GPhA's proposal on prioritization scheme discussion continues
 - A fair, objective, reasonable, and unbiased priority proposal to aid FDA



GPhA: GDUFA Industry's Responsibilities

- GPhA develop White Paper on “ANDA Completeness and quality of ANDA Submissions” that explores ways to and mechanisms to improve quality of submissions
- Track number of 1st cycle ANDA approval data



New Business



PAG

FDA: Program Alignment Group (PAG)

Howard Sklamberg



FDA: Office of Generic Drugs (OGD) Policy

Keith Flanagan



FDA: GDUFA Update

- GDUFA FAQ document and Glossary
 - FAQ
<http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm385694.htm>
 - Glossary:
<http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm385500.htm>
- ANDA status notification project (Feb 2014)
 - 2859 updated status on applications provided to industry



FDA: GDUFA Update

- Backlog Update

Backlog Progress

| As of 1/24/2014: | | | |
|---------------------------------------|----------|------|------------|
| | Original | PAS | Total |
| # Backlog | 2866 | 1882 | 4748 |
| # Submissions w 1st Action | 1151 | 973 | 2124 |
| % Submissions Complete | 40% | 52% | 45% |



Wrap-up and Next Steps