
MEETING MINUTES

SUBJECT: FDA-GPhA Board of Directors (BOD) Quarterly Meeting

DATE: November 19, 2013

FDA ATTENDEES:

Janet Woodcock - Center for Drug Evaluation and Research (CDER)
Robert Guidos - CDER/Office of the Center Director
Kathleen ("Cook") Uhl - Office of Generic Drug (OGD)
Robert West - OGD
Mary Dempsey - OGD
Jason Woo – OGD
Robert Lionberger - OGD
Keith Flanagan - OGD
Thomas Hinchliffe - OGD
Christina Kirby – OGD
Lawrence Yu – Office of Pharmaceutical Science (OPS)
Mary Beth Clarke - Office of Executive Programs (OEP)
Virginia Behr – CDER Ombudsman
Douglas Stearn - Office of Compliance
Ellen Morrison Office of Regulatory Affairs (ORA)
Theresa Mullin - Office of Strategic Programs (OSP)
Russell Wesdyk - OSP
Manju Thomas - OSP
Katherine Yang - OSP

SPONSOR ATTENDEES:

GPhA Member Company attendees:

Mylan	Tony Mauro – President
Momenta	Craig Wheeler – President
Zydus	Joe Renner – President
Ranbaxy	Chuck Caprariello – VP Government Affairs
Teva	Scott Tomsy – VP US Regulatory Affairs
Impax	Marcy Macdonald – VP Regulatory Affairs
Perrigo	Richard Stec – VP Regulatory Affairs
Fresenius-Kabi	Molly Rapp – VP Regulatory Affairs
Sandoz	Nicholas Tantillo – VP Regulatory Affairs
Actavis	Beth Brannan – VP Generic Regulatory Affairs
Hospira	Lisa Skeens – SVP Global Regulatory Affairs
Amneal	Candis Edwards – VP Regulatory Affairs
Apotex	Kiran Krishnan – VP Regulatory Affairs

GPhA attendees:

Ralph Neas
David Gaugh
Gordon Johnston
Mark Hendrickson

Agenda (for reference):

- I. Introductions
- II. Old Business /Action Item Follow Up From Last Meeting:
 - A. Easily Correctable Deficiencies GPhA
ECD Expectations and Statistics
 - B. Pre-CR Major Deficiencies Prior to Complete Response GPhA
 - C. Prioritizing Review Process of ANDAs FDA
During the Non-goal Years
 - D. Previously Proposed Priority Review System for ANDAs GPhA
- III. New Business
 - A. Office of Pharmaceutical Quality (OPQ) Reorganization FDA
 - B. Office of Generic Drugs (OGD) - Policy FDA
 - C. GDUFA Accomplishments and Overview FDA
 - D. GDUFA Industry Responsibilities GPhA
Quality of ANDA Submissions
- IV. Wrap-up and Next Steps

Topics Discussed/Action Items:

1. GDUFA Goals and commitments were discussed. (slide 5, 6)
2. GPhA's Easily Correctable Deficiency (ECD) expectations and statistics. (slide 8)
 - GPhA was unable to provide data on industry's experience with ECDs and feedback on their ability to successfully address deficiencies within 10 business days.
 - GPhA has formed a workgroup consisting of members from the BOD. The workgroup is in a process of creating an ECD document which contains data on their experience thus far on commonly requested ECDs, ECDs the applicant could not respond to in 10 business days and reasons why they were unable to respond within the business 10 days. This document expects to be provided to the FDA in 10 days (November 29, 2013) from this quarterly BOD meeting.
 - GPhA has requested the FDA to assist in data collection. GPhA would like the FDA to monitor and track the percentage of unanswered ECDs along with the reasons given by applicants on why they are unable to respond within the 10 business days

Action item:

- GPhA: Agreed that they need to complete this and expected to provide a document/paper to FDA 10 days (November 29, 2013) from this quarterly BOD meeting.
 - FDA: Begin to collect interim data and statistics on industry's rationale and reasons for not responding to ECDs within the defined 10 day timeframe.
3. Issuing a subset of Major deficiencies prior to Complete Response. (slide 9)
- GPhA was unable to provide a list of concrete examples representing Pre-CR Major deficiencies.
 - GPhA has formed a workgroup similar to above consisting of members from the BOD, and will create and provide a document listing specific examples of what they believe constitutes as Pre-CR Major deficiencies. This document expects to be provided to the FDA in 10 days (November 29, 2013) from this quarterly BOD meeting

Action item:

- GPhA: Provide a list of concrete examples representing the pre-CR subset of Major deficiencies.
 - GPhA/FDA: Keith Flanagan has agreed to facilitate as the point of contact for GPhA to follow up with to produce agreement or paper by end of December
4. Prioritizing Review Process of ANDAs (during non-goal years) was discussed. (slide 10 and web printout entitled "Activities Report of the Generic Drug Program")
- FDA to establish internal goals for all cohorts to prioritize non-goal vs. goal year review items.
 - FDA Activities report will be updated monthly
 - Report details monthly actions and receipts.
 - <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm375079.htm>

Action item:

- FDA: Break out statistics based on priority cohorts and paragraph filing (paragraph 3, 4, etc.) with details on ins and outs.
- FDA Activities report will be updated monthly and posted on web site: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm375079.htm>

5. Follow up to GPhA proposal for prioritizing review of unapproved ANDAs during the non-goal years. GPhA to re-examine proposal with respect to each applicant providing priority spreadsheets to FDA
 - GPhA still working to draft a document to provide clarification on “to whom or where would these lists would be sent” and “what response does the submitter expect to receive from FDA after sending”, will provide in the coming weeks.
 - FDA indicated that a quarterly spreadsheet from each applicant detailing their current priority ranking in not feasible. FDA working on priority cohorts that represent fair and unbiased review goals for all industry submissions regardless of GPhA membership.
 - FDA would like plan to be apprised in a proactive way of all target patent dates.

Action item:

GPhA: Provide a fair, objective, reasonable, unbiased priority proposal it would like to propose/aid FDA in development/refinement of current thinking presented earlier.

6. Office of Pharmaceutical Quality (OPQ) Reorganization overview was detailed by FDA. Additionally, Office of Compliance explained details of a minor reorganization accompanying the OPQ reorganization, specifically reorganizing domestic and international manufacturing compliance divisions to remove the distinction between the two, in recognition of the blending of the two in today's increasingly global supply chain and creating a policy staff that will develop compliance policies for manufacturing quality.
7. Overview of OGD Policy was presented.
 - Anticipate to publish key policy documents (MAPPS, Dockets, Guidances): review prioritization, application quality/multiple review cycles issues, amendments (major, minor, delaying, ECD) tiers, dispute resolution, supplement guidance (prior approval, changes being effected, amendments to prior approval, bundling changes, etc.), and controlled correspondences
 - Goal is to get these out as soon as possible so they can be finalized before FY15.
8. Overview of current GDUFA accomplishments was discussed. (slide 15-26)
9. GDUFA Industry Responsibilities: *Quality of ANDA Submissions* (slide 27)

The success of GDUFA is a shared responsibility. FDA is hiring, reorganizing, and revamping our processes and procedures to meet the GDUFA mandates. It is incumbent upon industry to improve the quality of its submissions in order for the GDUFA goals to be met. GPhA was tasked at the last quarterly meeting to explore ways to and mechanisms to improve quality of submissions and

present/discuss at next quarterly meeting. GPhA indicated that they are still working on this document which will aide both members and non-members and will provide to FDA upon completion.

FDA reported that ANDA application deficiencies are repetitive. OGD has provided numerous presentations and webinars to industry and the same deficiencies are submitted and resubmitted time and again. GPhA requested beginning a dialogue to address improving the quality of submissions. FDA referred back to the upcoming policy initiative to open a docket with respect to application quality/multiple review cycles issues. It is critical that industry improve efforts to increase the quality of applications to ensure that the GDUFA program is a success.

Action item:

GPhA: Develop and provide FDA a document (described as a white paper on “ANDA Completeness and quality of an ANDA Submissions”) that explores ways to and mechanisms to improve quality of submissions.

GPhA: Track the number of 1st cycle Approvals

10. Wrap-up

Action item:

FDA: provide activities report updates monthly on publically available website, outline process updates at next meeting, and provide data on P3/P4 and drug shortage

CC:

Janet Woodcock, CDER

David Gaugh, GPhA

Drugs

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Activities Report of the Generic Drug Program

GDUFA Year	10/12	11/12	12/12	1/13	2/13	3/13	4/13	5/13	6/13	7/13	8/13	9/13	Total Yr 1	10/13
Actions This Month														
Refuse to Receive (RTR)	9	10	4	14	10	15	16	2	17	14	19	20	150	30
Withdrawals	3	11	10	10	5	3	24	12	4	9	10	6	107	19
Approvals	35	34	39	29	43	49	41	32	31	45	31	31	440	20
Tentative Approvals	11	10	4	4	11	6	18	7	2	11	7	4	95	4
Complete Responses (CR)	126	130	125	97	104	73	104	96	94	92	105	105	1251	113
Drug Master File Complete Assessment (DMF CA)	18	127	76	189	154	144	147	124	121	178	202	219	1699	181
Submissions This Month														
Abbreviated New Drug Applications (ANDA)	75	56	163	58	51	86	74	46	74	102	83	100	968	41
Amendments - Originals														
To Backlog ANDAs	182	145	127	173	148	137	173	137	129	124	134	162	1771	152
To Cohort Yr 1 ANDAs	1	2	5	3	3	8	10	13	13	22	15	27	122	22
To Cohort Yr 2 ANDAs	0	0	0	0	0	0	0	0	0	0	0	0		2
Amendments - Supplements														
To Backlog Prior Approval Supplements (PAS)	38	55	32	37	35	40	39	23	33	34	37	34	437	28
To Cohort Yr 1 PASs	3	13	41	35	39	58	39	45	22	14	53	54	416	15
To Cohort Yr 2 PASs	0	0	0	0	0	0	0	0	0	0	0	0		27
Tier Amendments	0	0	0	0	0	0	0	0	0	0	0	0		0
Tier 1A														0
Tier 1B														0
Tier 1C														0
Tier 2														0
Drug Master Files (DMF)	99	63	105	70	71	102	85	64	64	98	72	131	1024	64
Controls	77	46	56	62	84	74	93	101	106	115	83	56	953	81
GDUFA Post CR Meeting Requests *														25
STATUS	Number													Number
Canceled														2
Complete														14
Denied														2
Granted														0
Pending														7
Post CR Meeting Requests This month	0	1	0	0	1	0	4	4	4	2	3	4	23	2