MEETING MINUTES

SUBJECT: FDA-GPhA Quarterly Meeting

DATE: March 23, 2015

FDA ATTENDEES:

Janet Woodcock - Center for Drug Evaluation and Research (CDER)
Robert Guidos - CDER
Kathleen ("Cook") Uhl - Office of Generic Drug (OGD)
Mike Ahmadi – OGD
Mary Dempsey - OGD
Dale Connor – OGD
Keith Flanagan – OGD
Derek Griffing – OGD
Thomas Hinchliffe – OGD
Mike Jones – OGD
Edward Kim – OGD
Robert Lionberger – OGD
Paula McKeever - OGD
Martha Nguyen – OGD
Linda Park – OGD
John Peters – OGD
Trueman Sharp – OGD
Edward Sherwood – OGD
Martin Shimer – OGD
Aaron Sigler – OGD
Maryll Toufanian – OGD
Trang Tran – OGD
Jason Woo – OGD
Lucie Yang – OGD
Grail Sipes - Office of Regulatory Policy (ORP)
Lawrence Yu– Office of Pharmaceutical Science (OPQ)
Ashley Boam – OPQ
Giuseppe Randazzo – OPQ
Glen Smith - OPQ
Hilmar Hamann – Office of Strategic Programs (OSP)
Ryan Conrad – OSP
Marta Wosinska – OSP
Melinda Plaisier - Office of Regulatory Affairs (ORA)
Alonza Cruse - ORA
Ilisa Bernstein – Office of Compliance (OC)
Sean Kassim – OC
John Kadavil – Office of Translational Science (OTS)
Bill Taylor - OTS
Mary Beth Clarke – Office of Executive Programs (OEP)
Virginia Behr – OEP
Kristina Lauritsen – OEP
Kristofer Baumgartner – Office of Communications (OCOMM)
Cherryn Chang – OCOMM
Jordana O'Grady – OCOMM

SPONSOR ATTENDEES:

GPhA Attendees:

Momenta	Craig Wheeler – President and Chair of the GPhA Board
Mylan	Marcie McClintic Coates – Vice President, Regulatory Policy and GPhA Board Member
Par	Tony Pera – Senior Vice President
Impax	Marcy Macdonald – Vice President, Regulatory Affairs and GPhA Board Member
Apotex	Kiran Krishnan – Vice President Regulatory Affairs
Teva	Scott Tomsky – Vice President, Regulatory Affairs
Fresenius-Kabi	Surendra Tyagi – Senior Vice President, Regulatory Affairs
Sandoz	Nick Tantillo – Vice President, Regulatory Affairs
Heritage	Pablo Davila – Vice President, Regulatory Affairs
Amneal	Candis Edwards – Vice President, Regulatory Affairs
Lupin	William McIntyre – Senior Vice President, Regulatory Affairs
GPhA	Ralph Neas
GPhA	David Gaugh
GPhA	Lisa Tan
GPhA	Mark Hendrickson

Agenda (for reference):

I)	Introduction	All
II)	OPQ Organizational Structure	FDA
III)	Time to Approval/Action	FDA
IV)	GDUFA 1 Operations Update	FDA
V)	QMS Update	FDA
VI)	Mechanics of Paragraph III and IV approvals	FDA
VII)	Wrap-up and Next Steps	All

Topics Discussed:

1. The Office of Pharmaceutical Quality structure was discussed (slide 4).

2. Measuring ANDA review timelines focusing on time to approval and time to first action was discussed (slides 6-15)

3. GDUFA 1 operational update (slides 16-25)

    - Update on operational activities highlighting various communication initiatives
    - Update on progress with FY15 submitted controlled correspondences
    - Update on ANDA statistics

4. QMS Update provided (slides 27-35)

5. Complex issues relating to First Generic ANDAs and discussion on mechanisms to ensure timely First Generic approvals provided (slides 36-68)

6. Wrap-up

    - Proposed topics for next meeting:

        - Mutual Reliance Initiative (Program Alignment Group) Update
        - Inspections and interaction with Target Action Dates
        - ORA Inspection Program Update
        - Office of Compliance Program Update
        - OPQ/Office of Surveillance Program and Selection Model Update
        - OPQ/Office of Process and Facilities Inspection (pre-approval and post-approval) Program Update
        - OTS/Office of Study Integrity and Surveillance Program Update

Action items:

FDA:

- Discuss/update inspection issues for bioequivalence/bioanalytical sites at the June meeting.
- Describe Status of pre October 1, 2014 control correspondences.
- FDA will evaluate GPHAs requests on communication initiatives.

GPhA:

- GPHA will follow up with Keith Flanagan if they have any additional questions on the time to approval issues.

CC:
Janet Woodcock, CDER

David Gaugh, GPhA