

# MEETING MINUTES

SUBJECT: FDA-GPhA Quarterly Meeting

DATE: June 11, 2015; 1:00 - 400pm

## FDA ATTENDEES:

CDER	Janet Woodcock Richard Moscicki Robert Guidos	Robert Lionberger Denise McKan Paula McKeever Martha Nguyen Linda Park
OEP	Mary Beth Clarke Heather Brown Virginia Behr Kristina Lauritsen	Carlene Randolph Peter Rickman Trueman Sharp Edward Sherwood
OC	Ilisa Bernstein Cynthia Schnedar David Burrow Sean Kassim	Jason Woo Lucie Yang
		OM Drew Carlton
OGD	John Peters Thushi Amini Mary Dempsey Benjamin Chacko Dale Connor Dat Doan Keith Flanagan Derek Griffing Thomas Hinchliffe Mike Jones Jasmeet Kalsi Edward Kim	OPQ Lawrence Yu Brian Hasselbalch Christine Moore Giuseppe Randazzo Susan Rosencrance Glen Smith
		ORA Melinda Plaisier Alonza Cruse Ann Marie Montemurro Ellen Morrison
		OTS John Kadavil

## INDUSTRY ATTENDEES:

Momenta	Craig Wheeler – President and Chair of the GPhA Board
Apotex	Jeremy Desai – President and CEO, GPhA Board Member
Apotex	Kiran Krishnan – Vice President, Regulatory Affairs
Mylan	Rajiv Malik – President
Mylan	Marcie McClintic-Coates – Vice President, Regulatory Policy and GPhA Board Member
Impax	Marcy Macdonald – Vice President, Regulatory Affairs and GPhA Board Member
Teva	Scott Tomsy – Vice President, Regulatory Affairs
Teva	Jim Ottinger – Senior Vice President, Global Regulatory Affairs
Par	David Quiggle, Senior Director, Regulatory Affairs
Perrigo	Rich Stec – Vice President, Regulatory Affairs
Perrigo	Jatin Shah – Senior Vice President, Global Regulatory Affairs
Fresenius-Kabi	Scott Meacham – President
Fresenius-Kabi	Molly Rapp – Vice President, Regulatory Affairs
Hospira	Lisa Skeens – Corporate Vice President, Global Regulatory Affairs
Hospira	Julie Reed – Vice President, Government Affairs and GPhA Board Member
Sandoz	Anthony Mafia – Vice President, Regulatory Affairs
Sandoz	Nick Tantillo – Vice President, Regulatory Affairs
Heritage	Pablo Davila – Vice President, Regulatory Affairs
Sun	Robert Femia – Vice President, Regulatory Affairs
Amneal	Jim Luce – Executive Vice President
Amneal	Candis Edwards – Vice President, Regulatory Affairs
Zydus	G. Srinivas – Sr. Director, Regulatory Affairs
Lupin	William McIntyre – Senior Vice President, Regulatory Affairs
Actavis	Beth Brennen – Vice President, Regulatory Affairs
GPhA	Ralph Neas David Gaugh Lisa Tan Mark Hendrickson Gordon Johnston

**Agenda (for reference):**

I.	GPhA Board Opening Statements	GPhA
II.	Generic Drug Program Update	FDA
III.	Q&A / Discussion	All
IV.	ORA Inspection Program Update	FDA
V.	OPQ/Office of Process and Facilities	FDA
VI.	Pre-Approval Inspections Update	FDA
VII.	OPQ/Office of Surveillance Program Update	FDA
VIII.	OTS/Office of Study Integrity and Surveillance Inspection Program Update	FDA
IX.	Wrap Up and Next Steps	FDA

**Topics Discussed:**

1. Craig Wheeler provided opening statements on behalf of the GPhA Board.
2. Ted Sherwood provided a Generic Drug Program update (slides 3-15)
3. Alonza Cruse provided an Office of Regulatory Affairs Inspection Program update (slides 17-22)
4. Russ Wesdyk provided an Office of Surveillance update (slides 41-52)
5. Christine Moore provided an Office of Process and Facilities and Pre-approval Inspection update (slides 23-40)
6. Sean Kassim provided an Office of Study Integrity and Surveillance Inspection Program update (slides 53-61)
7. Wrap-up

CC:  
Janet Woodcock, CDER

David Gaugh, GPhA