Table 3. PDUFA IV Meetings – Technical Discussions with Regulated Industry Pre-Market Review Subgroup

Date Time Length	Subjects	Participants
3/24/06 10:00-12:00 pm 2 hours	• Administrative matters regarding meeting times, dates and location • Ground rules for group conduct • Presentation of FDA issues surrounding PDUFA pre-market review • Presentation of industry issues surrounding PDUFA pre-market review	**FDA:** John Jenkins, CDER; Robert Yetter, CBER Kim Colangelo, CDER; Kevin Fain, OCC Christopher Joneckis, CBER Michael Lanthier, CDER **PhRMA:** Bruce Burlington, Wyeth; Alan Goldhammer, PhRMA Sharon Olmstead, Schering Plough **BIO:** Roy Baranello, Wyeth; Andrew Emmett, BIO Kay Holcombe, Genzyme; Sara Radcliffe, BIO
04/07/06 10:00-12:00 pm 2 Hours	• Discuss proposal regarding postmarketing study commitments • Discuss possible performance goals for resubmissions to prior approval manufacturing supplements • Discuss meeting management proposals • FDA response to industry data requests	**FDA:** John Jenkins, CDER; Robert Yetter, CBER Kim Colangelo, CDER; Michael Lanthier, CDER Armando Oliva, CDER **PhRMA:** Alan Goldhammer, PhRMA Sharon Olmstead, Schering Plough **BIO:** Roy Baranello, Wyeth; Doug Dobak, AstraZeneca Andrew Emmett, BIO; Kay Holcombe, Genzyme Sara Radcliffe, BIO
04/21/06 10:00-12:00 pm 2 Hours	• Proposal regarding labeling discussions • Discuss meeting management proposals • FDA response to data requests for commercial INDs submitted, clinical holds of commercial INDs, and clinical special protocol assessments submitted • Discuss Postmarketing Study	**FDA:** John Jenkins, CDER; Robert Yetter, CBER Kim Colangelo, CDER; Chris Joneckis, CBER Michael Lanthier, CDER ; Robert Meyer, CDER Lynn Whipkey Mehler, FDA (via telephone) **PhRMA:**

	Commitment proposals	Bruce Burlington, Wyeth; Alan Goldhammer, PhRMA Greg Brophy, Lilly (via telephone) Sharon Olmstead, Schering Plough **BIO:** Roy Baranello, Wyeth; Doug Dobak, AstraZeneca Kay Holcombe, Genzyme; Sara Radcliffe, BIO
05/05/06 10:00-12:00 pm 2 Hours	• Discuss proposal on Prior Approval Manufacturing Supplement resubmission performance goals • Discussion of current performance goals that adversely impact FDA productivity and efficiency • Discussion of ways to improve application quality • Discussion of alternative methods to achieve goals regarding Postmarketing study commitments and labeling • Timeline for Steering committee presentations	**FDA:** John Jenkins, CDER; Robert Yetter, CBER Kim Colangelo, CDER; Chris Joneckis, CBER Robert Meyer, CDER; David Morley, CDER **PhRMA:** Bruce Burlington, Wyeth; Alan Goldhammer, PhRMA Greg Brophy, Lilly (via telephone) Sharon Olmstead, Schering Plough **BIO:** Roy Baranello, Wyeth; Andrew Emmett, BIO Doug Dobak, AstraZeneca ; Kay Holcombe, Genzyme Sara Radcliffe, BIO
05/19/06 10:00-12:00 pm 2 Hours	• Discussion of critical path • Discussion of Continuous Marketing Application (CMA) Pilots 1 and 2 • Discussion of Prior Approval Manufacturing Supplement resubmission performance goals • Discussion of proposal to eliminate the goal regarding independent consultants at meetings to discuss biotechnology clinical trial protocols • Discuss inclusion of additional information in meeting requests • Continued group discussion of ways to improve application quality	**FDA:** John Jenkins, CDER; Robert Yetter, CBER Kim Colangelo, CDER; Chris Joneckis, CBER Michael Lanthier, CDER; Robert Meyer, CDER Rachel Behrman, FDA; Howard Chazin, CDER/FDA **PhRMA:** Bruce Burlington, Wyeth (via telephone) Alan Goldhammer, PhRMA Sharon Olmstead, Schering Plough Greg Brophy, Lilly **BIO** Roy Baranello, Wyeth; Doug Dobak, AstraZeneca Andrew Emmett, BIO (via telephone) Kay Holcombe, Genzyme Sara Radcliffe, BIO
06/02/06 9:00-12:00 pm	• FDA presentation of special study on time/level of effort	**FDA:** John Jenkins, CDER;

3 Hours	requirements to respond to meetings and special protocol assessment requests • FDA presentation of modified workload adjuster proposal • Discussion of proposal to discontinue CMA Pilots • Discuss inclusion of additional information in meeting requests	Robert Yetter, CBER Kim Colangelo, CDER; Michael Lanthier, CDER Lynn Whipkey Mehler, FDA (via telephone) Robert Meyer, CDER Howard Chazin, CDER/FDA Jonathan Mathieu, FDA **PhRMA:** Bruce Burlington, Wyeth; Alan Goldhammer, PhRMA Sharon Olmstead, Schering Plough Greg Brophy, Lilly **BIO:** Roy Baranello, Wyeth; Andrew Emmett, BIO Doug Dobak, AstraZeneca; Kay Holcombe, Genzyme Sara Radcliffe, BIO
06/16/06 10:00-12:00 pm 2 Hours	• Discussion of critical path to drug development • Discussion of proposal to discontinue CMA Pilots • Continued discussion of proposals intended to improve application quality	**FDA:** John Jenkins, CDER; Robert Yetter, CBER Kim Colangelo, CDER; Chris Joneckis (via telephone) Michael Lanthier, CDER; Robert Meyer, CDER Lynn Whipkey Mehler, FDA (via telephone) Rachel Behrman, FDA Theresa Mullin, FDA (via telephone) Howard Chazin, CDER/FDA; **PhRMA:** Bruce Burlington, Wyeth; Alan Goldhammer, PhRMA Greg Brophy, Lilly; Sharon Olmstead, Schering Plough **BIO:** Andrew Emmett, BIO (via telephone) Doug Dobak, AstraZeneca Kay Holcombe, Genzyme; Sara Radcliffe, BIO
06/30/06 9:00-12:00pm 3 Hours	• Discussion of workload adjuster proposal • Continued discussion of proposals intended to improve application quality • Discussion of savings from the elimination of CMA pilot programs	**FDA:** John Jenkins, CDER; Chris Joneckis, CBER Kim Colangelo, CDER ; Michael Lanthier, CDER Robert Yetter, CBER (via telephone) Jonathan Mathieu, FDA Lynn Whipkey Mehler, FDA (via telephone) Howard Chazin, CDER/FDA Robert Meyer, CDER;

		PhRMA: Bruce Burlington, Wyeth; Alan Goldhammer, PhRMA Jeff Jeffress, Boston Consulting Group Greg Brophy, Lilly **BIO:** Andrew Emmett, BIO; Roy Baranello, Wyeth Doug Dobak, AstraZeneca; Kay Holcombe, Genzyme Sara Radcliffe, BIO
7/14/06 9:00-12:00 pm 3 Hours	• Discussion of FDA meeting and SPA workload • Discussion of the modified workload adjuster proposal	**FDA:** John Jenkins, CDER; Robert Yetter, CBER Kim Colangelo, CDER (via telephone) Chris Joneckis, CBER Michael Lanthier, CDER; Howard Chazin, CDER/FDA Lynn Whipkey Mehler, FDA (via telephone) Jonathan Mathieu, FDA Robert Meyer, CDER; Theresa Mullin, FDA Beth Duvall-Miller, CDER; **PhRMA:** Bruce Burlington, Wyeth; Alan Goldhammer, PhRMA Greg Brophy, Lilly; Martha Brumfield, Pfizer Sharon Olmstead, Schering Plough Jeff Jeffress, Boston Consulting Group (via telephone) **BIO:** Andrew Emmett, BIO; Roy Baranello, Wyeth Doug Dobak, AstraZeneca; Kay Holcombe, Genzyme Sara Radcliffe, BIO
7/28/06 9:00-12:00 pm 3 Hours	• Discussion of proposed projects to expedite drug development	**FDA:** John Jenkins, CDER; Robert Yetter, CBER Kim Colangelo, CDER; Chris Joneckis, CBER Lynn Whipkey Mehler, FDA (via telephone) Robert Meyer, CDER; Nancy Derr, FDA; Shirley Murphy, CDER Robert Temple, CDER; Janet Woodcock, FDA Elizabeth Kamp, FDA (student volunteer)

		PhRMA: Bruce Burlington, Wyeth; Alan Goldhammer, PhRMA Greg Brophy, Lilly; Sharon Olmstead, Schering Plough Jeff Jeffress, Boston Consulting Group **BIO:** Andrew Emmett, BIO; Roy Baranello, Wyeth Doug Dobak, AstraZeneca; Kay Holcombe, Genzyme Sara Radcliffe, BIO (via telephone)
8/11/06 9:00-12:00 pm 3 Hours	• Further discussion of proposed projects to expedite drug development • Discussion of GRMP review timelines • Discussion of a path forward for modified workload adjuster proposal • Plans for achieving wrap-up of subgroup discussions by mid-September	**FDA:** John Jenkins, CDER; Kim Colangelo, CDER; Chris Joneckis, CBER Lynn Whipkey Mehler, FDA (via telephone) Howard Chazin, CDER/FDA Shiew Mei Huang, CDER (via telephone) Shirley Murphy, CDER Robert O'Neill, CDER **PhRMA:** Bruce Burlington, Wyeth; Alan Goldhammer, PhRMA Greg Brophy, Lilly; Martha Brumfield, Pfizer Derrick Fu, PhRMA (via telephone) **BIO** Roy Baranello, Wyeth; Doug Dobak, AstraZeneca Kay Holcombe, Genzyme (via telephone) Sara Radcliffe, BIO
8/18/06 9:00-11:00am 2 Hours	• Discussion of proposed language for goals letter regarding meeting management goals • Discussion of FDA proposal regarding GRMP review timelines	**FDA:** John Jenkins, CDER; Robert Yetter, CBER Kim Colangelo, CDER; Mike Lanthier, CDER **PhRMA:** Alan Goldhammer, PhRMA; Martha Brumfield, Pfizer Sharon Olmstead, Schering Plough **BIO:** Andrew Emmett, BIO; Roy Baranello, Wyeth Doug Dobak, AstraZeneca; Sara Radcliffe, BIO Kay Holcombe, Genzyme (via

		telephone)
8/25/06 9:00-12:00 pm 3 Hours	• Discussion of proposed projects to expedite drug development • Review of proposed goals letter language, including overall revisions for PDUFA first-cycle initiative and added section on notification of planned review timelines	**FDA:** John Jenkins, CDER; Robert Yetter, CBER Kim Colangelo, CDER; Mike Lanthier, CDER Lynn Whipkey Mehler, FDA (via telephone) Robert Meyer, CDER Howard Chazin, CDER/FDA Kathryn Carbone, CBER Shirley Murphy, CDER; Robert Temple, CDER Robert O'Neill, CDER (via telephone) **PhRMA:** Alan Goldhammer, PhRMA; Greg Brophy, Lilly Martha Brumfield, Pfizer; Sharon Olmstead, Schering Plough (via telephone) **BIO:** Andrew Emmett, BIO; Roy Baranello, Wyeth Doug Dobak, AstraZeneca ; Sara Radcliffe, BIO Kay Holcombe, Genzyme (via telephone)
9/1/06 9:00-11:00 am 2 Hours	• Discussion of Expediting Drug Development Projects proposal • Discusion of proposed goals letter language	**FDA:** Robert Yetter, CBER; Howard Chazin, CDER Lynn Whipkey Mehler, FDA (via telephone) Beth Duvall-Miller, CDER **PhRMA:** Greg Brophy, Lilly (via telephone) Alan Goldhammer, PhRMA Sharon Olmstead, Schering Plough Bruce Burlington, Wyeth (via telephone) **BIO:** Sara Radcliffe, BIO (via telephone) Roy Baranello, Wyeth Doug Dobak, AstraZeneca (via telephone) Kay Holcombe, Genzyme (via telephone)
9/8/06 9:00-12:00 pm 3 Hours	• Discussion of proposals regarding "Expediting Projects" • Review of proposed goals letter language on the notification of planned review	**FDA:** John Jenkins, CDER; Robert Yetter, CBER Kim Colangelo, CDER; Mike Lanthier, CDER

	timelines	Robert Meyer, CDER (via telephone) **PhRMA:** Alan Goldhammer, PhRMA; Greg Brophy, Lilly Martha Brumfield, Pfizer; Sharon Olmstead, Schering Plough (via telephone) **BIO:** Andrew Emmett, BIO; Roy Baranello, Wyeth Doug Dobak, AstraZeneca (via telephone) Kay Holcombe, Genzyme