

Table 2. PDUFA IV Meetings – Technical Discussions with Regulated Industry Finance Subcommittee

Date Time Length	Subjects	Participants
<p>4/7/06 1:30 to 3:30PM 2 hours</p>	<p>The following topics were discussed at the meeting:</p> <ul style="list-style-type: none"> • Future Meetings. • April 21st Meeting Agenda. 	<p>FDA: Russ Abbott, FDA/CDER Frank Claunts, FDA/OM Roger Eastep, FDA/CBER Kevin Fain, FDA/OCC Mike Jones, FDA/CDER Jerry Paull, FDA/CBER</p> <p>BIO: Andrew Emmett, BIO Mary McGrane, BIO Donna Peterson, BIO</p>
<p>4/21/06 1:30 to 3:30 PM 2 Hours</p>	<p>The following topics were discussed at the meeting:</p> <ul style="list-style-type: none"> • FDA Appropriated Budget. • Workload Adjuster. • Industry Financial Proposals. • FDA Financial Proposals. 	<p>FDA: Frank Claunts, FDA/OM Roger Eastep, FDA/CBER Kevin Fain, FDA/OCC Mike Jones, FDA/CDER Bob Linkous, FDA/CDER Martie Louviere, FDA/OC Jerry Paull, FDA/CBER</p> <p>BIO: Mary McGrane, BIO/Genzyme (Phone) Donna Peterson, BIO/Amgen (Phone) Sara Radcliffe, BIO</p> <p>PhRMA: Alan Goldhammer, PhRMA Don Sauer, PhRMA/Wyeth Lynne Tracey, PhRMA/P&G</p>
<p>5/5/06 1:30 to 3:30 PM 2 Hours</p>	<p>The following topics were discussed at the meeting:</p> <ul style="list-style-type: none"> • FDA Technical Proposals • Budget Amendment • Inflation Adjuster Proposal • White Oak Costs. • FDA Human Drug Review Process Overhead 	<p>FDA: Jane Axelrad, FDA/CDER Nancy Boocker, FDA/CDER Frank Claunts, FDA/OM Roger Eastep, FDA/CBER Kevin Fain, FDA/OCC Mike Jones, FDA/CDER Bob Linkous, FDA/CDER Martie Louviere, FDA/OC Jerry Paull, FDA/CBER</p> <p>BIO: Mary McGrane, BIO/Genzyme (by phone) Donna Peterson, BIO/Amgen Sara Radcliffe, BIO</p> <p>PhRMA:</p>

		<p>Alan Goldhammer, PhRMA Dave Keaney, PhRMA/Novartis Don Sauer, PhRMA/Wyeth Lynne Tracey, PhRMA/P&G (by phone)</p>
<p>5/19/06 1:30 to 3:30 PM 2 hours</p>	<p>The following topics were discussed at the meeting:</p> <ul style="list-style-type: none"> • Technical Proposals. • Inflation Adjustment Proposal. • FDA PDUFA III Cost Review. • PDUFA III Base Resources. • Unit Cost Data. • Financial Baseline • FTE Module. 	<p>FDA: Russ Abbott, FDA/CDER Jane Axelrad, FDA/CDER Nancy Boocker, FDA/CDER Frank Claunts, FDA/OM Roger Eastep, FDA/CBER Kevin Fain, FDA/OCC Mike Jones, FDA/CDER Bob Linkous. FDA/CDER Martie Louviere, FDA/OC Theresa Mullin, FDA/OC Jerry Paull, FDA/CBER</p> <p>BIO: Andrew Emmett, BIO Donna Peterson, BIO/Amgen Sara Radcliffe, BIO</p> <p>PhRMA: Alan Goldhammer, PhRMA Don Sauer, PhRMA/Wyeth Lynne Tracey, PhRMA/P&G</p>
<p>6/2/06 1:30 to 3:30 PM 2 hours</p>	<p>The following topics were discussed at the meeting:</p> <ul style="list-style-type: none"> • Technical Proposals. • Inflation Adjustment Proposal. • Review FDA Process for Estimating FTE/Dollars. • Inflation adjustment of user fee trigger for spending from appropriations 	<p>FDA: Jane Axelrad, FDA/CDER Nancy Boocker, FDA/CDER Frank Claunts, FDA/OM Roger Eastep, FDA/CBER Kevin Fain, FDA/OCC Mike Jones, FDA/CDER Bob Linkous. FDA/CDER Martie Louviere, FDA/OC Theresa Mullin, FDA/OC</p> <p>BIO: Andrew Emmett, BIO Donna Peterson, BIO/Amgen Sara Radcliffe, BIO Mary McGrane, BIO/Genzyme (by phone)</p> <p>PhRMA: Alan Goldhammer, PhRMA Don Sauer, PhRMA/Wyeth Lynne Tracey, PhRMA/P&G</p>
<p>6/16/06</p>	<p>The following topics were discussed at the meeting:</p> <ul style="list-style-type: none"> • FDA Contracts • Workload Adjuster Presentation. • Technical Amendments 	<p>FDA: Frank Claunts, FDA/OM Roger Eastep, FDA/CBER Kevin Fain, FDA/OCC Mike Jones, FDA/CDER Bob Linkous. FDA/CDER Martie Louviere, FDA/OC</p>

	<ul style="list-style-type: none"> • Remaining Technical Amendments. Inflation Adjustment Proposal. Financial Baseline Proposal. • Future Tasks. 	Jonathan Mathieu, FDA/OC Jerry Paull, FDA/CBER BIO: Andrew Emmett, BIO Donna Peterson, BIO/Amgen Sara Radcliffe, BIO Mary McGrane, BIO/Genzyme (by phone) PhRMA: Lynne Tracey, PhRMA/P&G
6/30/06 1:30 to 3:30 PM 2 hours	The following topics were discussed at the meeting: <ul style="list-style-type: none"> • PDUFA IV Enhancement Proposal Cost Summary. • Fees/Appropriations Relationship Models. • FDA Efficiencies. 	FDA: Nancy Boocker, FDA/CDER Frank Claunts, FDA/OM Roger Eastep, FDA/CBER Kevin Fain, FDA/OCC Mike Jones, FDA/CDER Bob Linkous, FDA/CDER Martie Louviere, FDA/OC Jerry Paull, FDA/CBER BIO: Andrew Emmett, BIO Donna Peterson, BIO/Amgen Sara Radcliffe, BIO Mary McGrane, BIO/Genzyme, (by phone) PhRMA: Alan Goldhammer, PhRMA Jeff Jeffress, The Boston Consulting Group Don Sauer, PhRMA/Wyeth Lynne Tracey, PhRMA/P&G (by phone)
7/14/06 1:30 to 3:30 PM 2 hours	The following topics were discussed at the meeting: <ul style="list-style-type: none"> • Slide Presentation. • Workload Adjuster. • Process Issues. 	FDA: Frank Claunts, FDA/OM Martie Louviere, FDA/OC Jonathan Mathieu, FDA/OC Theresa Mullin, FDA/OC Jerry Paull, FDA/CBER BIO: Andrew Emmett, BIO Donna Peterson, BIO/Amgen PhRMA: Alan Goldhammer, PhRMA Jeff Jeffress, The Boston Consulting Group
7/21/06 1:30 to 3:30 PM 2 hours	The following topics were discussed at the meeting: <ul style="list-style-type: none"> • FDA Revenue Estimates. • Inflation Adjustment. 	FDA: Frank Claunts, FDA/OM Roger Eastep, FDA/CBER Kevin Fain, FDA/OCC Mike Jones, FDA/CDER (by phone)

	<ul style="list-style-type: none"> • Workload Adjuster. 	<p>Jonathan Matheau, FDA/OP Jerry Paull, FDA/CBER</p> <p>BIO: Andrew Emmett, BIO Mary McGrane, BIO/Genzyme (by phone) Donna Peterson, BIO/Amgen Sara Radcliffe, BIO (by phone)</p> <p>PhRMA: Alan Goldhammer, PhRMA Jeff Jeffress, The Boston Consulting Group Lynne Tracey, PhRMA/P&G (by phone)</p>
<p>7/28/06 1:30 to 3:30 PM 2 hours</p>	<p>The following topics were discussed at the meeting:</p> <ul style="list-style-type: none"> • Pending Issues. • Workload Adjuster. 	<p>FDA: Frank Claunts, FDA/OM Nancy Boocker, FDA/CDER Roger Eastep, FDA/CBER Mike Jones, FDA/CDER Martie Louviere, FDA/OC Jonathan Matheau, FDA/OP Jerry Paull, FDA/CBER</p> <p>BIO: Andrew Emmett, BIO Donna Peterson, BIO/Amgen Sara Radcliffe, BIO (by phone)</p> <p>PhRMA: Alan Goldhammer, PhRMA Jeff Jeffress, The Boston Consulting Group Dave Keaney, PhRMA/Novartis Don Sauer, PhRMA/Wyeth (by phone) Lynne Tracey, PhRMA/P&G (by phone)</p>
<p>8/25/06 1:30 to 3:30 PM 2 hours</p>	<p>The following topics were discussed at the meeting:</p> <ul style="list-style-type: none"> • Draft Proposed Statutory and Legislative History Language. • Workload Adjuster. • Indirect Costs/Overhead. 	<p>FDA: Frank Claunts, FDA/OM Roger Eastep, FDA/CBER Kevin Fain, FDA/OCC Bob Linkous, FDA/CDER (by phone) Martie Louviere, FDA/OC Jonathan Matheau, FDA/OP Jerry Paull, FDA/CBER</p> <p>BIO: Andrew Emmett, BIO Mary McGrane, BIO/Genzyme (by phone) Donna Peterson, BIO/Amgen Sara Radcliffe, BIO (by phone)</p> <p>PhRMA: Alan Goldhammer, PhRMA</p>