

**Table 1. PDUFA IV Meetings – Technical Discussions with Regulated Industry Steering Group Meetings**

| Date<br>Time<br>Length                                  | Subjects   | Participants  |
|---|--|---|
| <p><b>10/25/05</b><br/>4:00 to 5:00 PM<br/>1 Hour</p>   | <ul style="list-style-type: none"> <li>• Upcoming PDUFA IV reauthorization</li> <li>• PDUFA IV technical discussion steering group and technical groups</li> <li>• Schedule of technical discussions</li> <li>• Data on PDUFA trends</li> <li>• Public accountability/Consultation on reauthorization</li> </ul> | <p><b>FDA:</b><br/>Theresa Mullin, OPPL<br/>Jane Axelrad, CDER (phone)<br/>Frank Claunts, OM<br/>Bob Yetter, CBER<br/>John Jenkins, CDER<br/>Malcolm Bertoni, OPPL<br/>Mark Gray, OCIO<br/>Fred Farmer, OCIO<br/>Paul Seligman, CDER (phone)<br/>Patricia Stewart, OPPL<br/>Ralph Lillie, CDER<br/>Ann Sullivan, OPPL<br/>David Horowitz, ORA</p> <p><b>PhRMA/BIO:</b><br/>Roy Baranello, Wyeth<br/>Andrew Emmett, BIO<br/>Donna Peterson, Amgen<br/>Alan Goldhammer, PhRMA<br/>Bob Pietrusko, Millennium<br/>Rachel Carle, Genzyme (phone)<br/>Scott Lassman, PhRMA<br/>Bruce Burlington, Wyeth<br/>Stacey Holdsworth, Eli Lilly<br/>Bill Rosen, Pfizer<br/>Lynne Tracey, Procter and Gamble<br/>Sharon Olmstead, Schering-Plough<br/>Kay Holcombe, Consultant to BIO<br/>Peter Loupos, Sanofi-Aventis (phone)</p> |
| <p><b>1/24/06</b><br/>3:00 to 4:30 PM<br/>1 ½ Hours</p> | <ul style="list-style-type: none"> <li>• FDA responses to the industry's data request in preparation for the upcoming PDUFA IV reauthorization.</li> </ul>   | <p><b>FDA:</b><br/>Theresa Mullin, OPPL<br/>Jane Axelrad, CDER<br/>Frank Claunts, OM<br/>Leonard Wilson, CBER<br/>John Jenkins, CDER<br/>Malcolm Bertoni, OPPL<br/>Ann Wion, OCC<br/>Fred Farmer, OCIO<br/>Deborah Henderson, CDER<br/>Robert Temple, CDER<br/>Ralph Lillie, CDER<br/>Nancy Boocker, CDER<br/>Michael Lanthier, CDER<br/>Patricia Stewart, OPPL</p> <p><b>PhRMA</b><br/>Alan Goldhammer, PhRMA</p>  |

|   |  |  |
|---|--|--|
|   |  | <p>Stacey Holdsworth, Eli Lilly<br/> Scott Lassman, PhRMA<br/> Jim Kotsanos, Eli Lilly<br/> Bill Rosen, Pfizer<br/> Gretchen Dieck, Pfizer<br/> Bruce Burlington, Wyeth<br/> Peter Loupos, Sanofi-Aventis<br/> Sharon Olmstead, Schering Plough<br/> Lynne Tracey, Procter &amp; Gamble<br/> Don Sauer, Wyeth<br/> Steve Tilton, PhRMA</p> <p><b>BIO:</b><br/> Alison Lawton, Genzyme Corporation<br/> Roy Baranello, Wyeth<br/> Donna Peterson, Amgen<br/> Bob Pietrusko, Millennium<br/> Sara Radcliffe, BIO<br/> Andrew Emmett, BIO</p>   |
| <p><b>2/14/06</b> Teleconference<br/> 3:00 to 4:00 PM<br/> 1 Hour</p> | <ul style="list-style-type: none"> <li>Discuss industry request for data on PDUFA program and postmarket safety</li> </ul>   | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Jane Axelrad, CDER<br/> Deborah Henderson, CDER<br/> Ralph Lillie, CDER<br/> Patricia Stewart, OPPL</p> <p><b>Industry:</b><br/> Alan Goldhammer, PhRMA<br/> Sara Radcliffe, PhRMA<br/> Donna Peterson, BIO<br/> Andrew Emmett, BIO</p>  |
| <p><b>3/16/06</b><br/> 1:00 to 4:00 PM<br/> 3 Hours</p>               | <ul style="list-style-type: none"> <li>Discuss FDA versus industry perspectives on PDUFA reauthorization.</li> <li>The meeting concluded with agreement to hold more detailed discussions of specific issues in subsequent meetings of technical subgroups.</li> </ul> | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Jane Axelrad, CDER<br/> Ann Wion, OCC<br/> Robert Yetter, CBER<br/> John Jenkins, CDER<br/> Malcolm Bertoni, OPPL<br/> Martha Louviere, OM<br/> Fred Farmer, OCIO<br/> Deborah Henderson, CDER<br/> David Horowitz, ORA<br/> Ralph Lillie, CDER<br/> Nancy Boocker, CDER<br/> John Gentile, OM<br/> Karen Meister, OL<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA</b><br/> Alan Goldhammer, PhRMA<br/> Tricia de Santis, Johnson and Johnson<br/> Lynne Tracey, Procter &amp; Gamble<br/> Sharon Olmstead, Schering Plough<br/> Bill Rosen, Pfizer<br/> Peter Loupos, Sanofi-Aventis</p> |

|  |   |   |
|--|---|---|
|  |   | <p>Bruce Burlington, Wyeth<br/> Tony Rogers, AstraZeneca<br/> Scott Lassman, PhRMA<br/> Don Sauer, Wyeth<br/> Annetta Beauregard, Eli Lilly</p> <p><b>BIO:</b><br/> Alison Lawton, Genzyme<br/> Kay Holcome, Genzyme<br/> Roy Baranello, Wyeth<br/> Amit Sachdev, BIO<br/> Donna Peterson, Amgen<br/> Sara Radcliffe, BIO<br/> Bob Pietrusko, Millennium<br/> Andrew Emmett, BIO</p>  |
| <p><b>3/30/06</b><br/> Teleconference<br/> 3:00 to 4:00 PM<br/> 1 Hour</p> | <ul style="list-style-type: none"> <li>• Status of subgroup activities and identification of issues for discussion at future Steering Group meetings.</li> <li>• Plans for subsequent meetings of technical subgroups including meeting schedules and specific issues that will be discussed first in the subgroups and then the Steering Group.</li> </ul> | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Jane Axelrad, CDER<br/> Ann Wion, OCC<br/> Robert Yetter, CBER<br/> John Jenkins, CDER<br/> Malcolm Bertoni, OPPL<br/> Martha Louviere, OM<br/> Fred Farmer, OCIO<br/> Deborah Henderson, CDER<br/> Nancy Boocker, CDER<br/> Ralph Lillie, CDER<br/> Roger McClung, HHS<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Tricia de Santis, Johnson and Johnson<br/> Lynne Tracey, Procter &amp; Gamble<br/> Sharon Olmstead, Schering Plough<br/> Bill Rosen, Pfizer<br/> Peter Loupos, Sanofi-Aventis<br/> Bruce Burlington, Wyeth<br/> Gretchen Dieck, Pfizer<br/> Tony Rogers, AstraZeneca<br/> Don Sauer, Wyeth<br/> Scott Lassman, PhRMA<br/> Annetta Beauregard, Eli Lilly</p> <p><b>BIO:</b><br/> Alison Lawton, Genzyme<br/> Kay Holcombe, Genzyme<br/> Roy Baranello, Wyeth<br/> Amit Sachdev, BIO<br/> Donna Peterson, Amgen<br/> Sara Radcliffe, BIO<br/> Bob Pietrusko, Millennium<br/> Andrew Emmett, BIO</p> |
| <p><b>4/27/06</b><br/> 1:00 to 4:00 PM</p>                                 | <ul style="list-style-type: none"> <li>• FDA funding, costs and efficiencies</li> </ul>   | <p><b>FDA</b><br/> Theresa Mullin, OPPL</p>   |

|   |  |  |
|---|--|--|
| <p>3 Hours</p>  | <ul style="list-style-type: none"> <li>• Quality of application submissions</li> <li>• FDA workload and productivity</li> </ul>                          | <p>Jane Axelrad, CDER<br/> John Jenkins, CDER<br/> Malcolm Bertoni, OPPL<br/> Frank Claunts, OM<br/> Fred Farmer, OCIO<br/> Deborah Henderson, CDER<br/> Nancy Boocker, CDER<br/> Ralph Lillie, CDER<br/> Roger McClung, HHS<br/> Karen Meister, OL<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Lynne Tracey, Procter &amp; Gamble<br/> Bruce Burlington, Wyeth<br/> Tony Rogers, AstraZeneca<br/> Annetta Beauregard, Eli Lilly<br/> Tricia de Santis, Johnson and Johnson (tcon)</p> <p><b>BIO:</b><br/> Alison Lawton, Genzyme<br/> Kay Holcombe, Genzyme<br/> Roy Baranello, Wyeth<br/> Amit Sachdev, BIO<br/> Donna Peterson, Amgen<br/> Sara Radcliffe, BIO<br/> Bob Pietrusko, Millennium<br/> Andrew Emmett, BIO</p> |
| <p><b>5/11/06</b><br/> 2:30 to 4:00 PM<br/> 1 ½ Hours</p> | <ul style="list-style-type: none"> <li>• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings</li> </ul> | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> John Jenkins, CDER<br/> Ann Wion, OCC<br/> Robert Yetter, CBER<br/> Frank Claunts, OM<br/> Malcolm Bertoni, OPPL<br/> Martha Louviere, OM<br/> Fred Farmer, OCIO<br/> Deborah Henderson, CDER<br/> Nancy Boocker, CDER<br/> Ralph Lillie, CDER<br/> Roger McClung, HHS<br/> Karen Meister, OL<br/> Howard Chazin, CDER<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Tricia de Santis, Johnson and Johnson<br/> Lynne Tracey, Procter &amp; Gamble<br/> Sharon Olmstead, Schering Plough<br/> Bill Rosen, Pfizer<br/> Annetta Beauregard, Eli Lilly<br/> Bruce Burlington, Wyeth<br/> Gretchen Dieck, Pfizer</p>   |

|   |  |   |
|---|--|---|
|   |  | <p>Tony Rogers, AstraZeneca<br/>Don Sauer, Wyeth<br/>Scott Lassman, PhRMA</p> <p><b>BIO:</b><br/>Alison Lawton, Genzyme<br/>Kay Holcombe, Genzyme<br/>Roy Baranello, Wyeth<br/>Amit Sachdev, BIO<br/>Donna Peterson, Amgen<br/>Sara Radcliffe, BIO<br/>Bob Pietrusko, Millennium<br/>Andrew Emmett, BIO</p>   |
| <p><b>5/25/06</b><br/>1:00 to 3:00 PM<br/>2 Hours</p> | <ul style="list-style-type: none"> <li>• Areas of concern that were expressed by the Patient Advocacy and Consumer Groups at the May 22 and 23, 2006 PDUFA IV stakeholder meetings with FDA</li> <li>• Finance subgroup technical proposals</li> <li>• Premarket group technical proposals regarding meeting management process</li> <li>• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings</li> </ul> | <p><b>FDA:</b><br/>Theresa Mullin, OPPL<br/>John Jenkins, CDER<br/>Ann Wion, OCC<br/>Robert Yetter, CBER<br/>Frank Claunts, OM<br/>Malcolm Bertoni, OPPL<br/>Martha Louviere, OM<br/>Fred Farmer, OCIO<br/>Deborah Henderson, CDER<br/>Nancy Boocker, CDER<br/>Ralph Lillie, CDER<br/>Michael Jones, CDER<br/>Karen Meister, OL<br/>Howard Chazin, CDER<br/>Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/>Alan Goldhammer, PhRMA<br/>Tricia de Santis, Johnson and Johnson<br/>Lynne Tracey, Procter &amp; Gamble<br/>Sharon Olmstead, Schering Plough<br/>Bill Rosen, Pfizer<br/>Annetta Beauregard, Eli Lilly<br/>Bruce Burlington, Wyeth<br/>Gretchen Dieck, Pfizer<br/>Tony Rogers, AstraZeneca<br/>Don Sauer, Wyeth<br/>Scott Lassman, PhRMA</p> <p><b>BIO:</b><br/>Alison Lawton, Genzyme<br/>Kay Holcombe, Genzyme<br/>Roy Baranello, Wyeth<br/>Amit Sachdev, BIO<br/>Donna Peterson, Amgen<br/>Sara Radcliffe, BIO<br/>Bob Pietrusko, Millennium<br/>Andrew Emmett, BIO</p> |
| <p><b>6/22/06</b><br/>1:00 to 4:00 PM<br/>3 Hours</p> | <ul style="list-style-type: none"> <li>• Premarket subgroup proposals for meeting management goals</li> </ul>  | <p><b>FDA:</b><br/>Theresa Mullin, OPPL<br/>John Jenkins, CDER (tcon)</p>   |

|   |   |  |
|---|---|--|
|   | <ul style="list-style-type: none"> <li>• CMA pilots</li> <li>• The Inflation Adjustor proposal</li> <li>• The model for the financial baseline for FY 2008</li> <li>• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings</li> </ul> | <p>Ann Wion, OCC<br/> Robert Yetter, CBER<br/> Frank Claunts, OM<br/> Malcolm Bertoni, OPPL<br/> Martha Louviere, OM<br/> Jane Axelrad, CDER<br/> Deborah Henderson, CDER<br/> Nancy Boocker, CDER<br/> Howard Chazin, CDER<br/> Roger McClung, HHS<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Tricia de Santis, Johnson and Johnson<br/> Lynne Tracey, Procter &amp; Gamble<br/> Sharon Olmstead, Schering Plough<br/> Bill Rosen, Pfizer<br/> Tony Rogers, AstraZeneca<br/> Bruce Burlington, Wyeth<br/> Scott Lassman, PhRMA</p> <p><b>BIO:</b><br/> Alison Lawton, Genzyme<br/> Kay Holcombe, Genzyme<br/> Roy Baranello, Wyeth<br/> Amit Sachdev, BIO<br/> Donna Peterson, Amgen<br/> Sara Radcliffe, BIO<br/> Bob Pietrusko, Millennium<br/> Andrew Emmett, BIO</p> |
| <p><b>7/6/06</b> Teleconference<br/> 1:00 to 2:30 PM<br/> 1 ½ Hours</p> | <ul style="list-style-type: none"> <li>• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings</li> <li>• Discussion of trends in appropriations for drug review</li> </ul>  | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Robert Yetter, CBER<br/> Ann Wion, OCC<br/> Malcolm Bertoni, OPPL<br/> Jane Axelrad, CDER<br/> Martha Louviere, OM<br/> Deborah Henderson, CDER<br/> Nancy Boocker, CDER<br/> Ralph Lillie, CDER<br/> Howard Chazin, CDER<br/> Roger McClung, HHS<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Tricia de Santis, Johnson and Johnson<br/> Bill Rosen, Pfizer<br/> Annetta Beauregard, Eli Lilly<br/> Bruce Burlington, Wyeth<br/> Gretchen Dieck, Pfizer<br/> Tony Rogers, AstraZeneca<br/> Don Sauer, Wyeth<br/> Scott Lassman, PhRMA</p>  |

|  |   |   |
|--|---|---|
|  |   | <p>Peter Loupos, Sanofi-Aventis</p> <p><b>BIO:</b><br/> Alison Lawton, Genzyme<br/> Kay Holcombe, Genzyme<br/> Roy Baranello, Wyeth<br/> Amit Sachdev, BIO<br/> Donna Peterson, Amgen<br/> Sara Radcliffe, BIO<br/> Bob Pietrusko, Millennium<br/> Andrew Emmett, BIO</p>   |
| <p><b>7/13/06</b><br/> Teleconference<br/> 1:00 to 2:00 PM<br/> 1 Hour</p> | <ul style="list-style-type: none"> <li>• IT Communications and Technical Interactions proposal</li> <li>• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings</li> </ul> | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Robert Yetter, CBER<br/> Ann Wion, OCC<br/> Malcolm Bertoni, OPPL<br/> John Jenkins, CDER<br/> Frank Claunts, OM<br/> Deborah Henderson, CDER<br/> Martha Louviere, OM<br/> Ralph Lillie, CDER<br/> Nancy Boocker, CDER<br/> Karen Meister, OL<br/> Margo Burnette, OCIO<br/> Roger McClung, HHS<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Tricia de Santis, Johnson and Johnson<br/> Lynne Tracey, Procter &amp; Gamble<br/> Sharon Olmstead, Schering Plough<br/> Bill Rosen, Pfizer<br/> Annetta Beauregard, Eli Lilly<br/> Bruce Burlington, Wyeth<br/> Gretchen Dieck, Pfizer<br/> Tony Rogers, AstraZeneca<br/> Peter Loupos, Sanofi-Aventis<br/> Scott Lassman, PhRMA</p> <p><b>BIO:</b><br/> Alison Lawton, Genzyme<br/> Kay Holcombe, Genzyme<br/> Roy Baranello, Wyeth<br/> Amit Sachdev, BIO<br/> Donna Peterson, Amgen<br/> Sara Radcliffe, BIO<br/> Andrew Emmett, BIO</p> |
| <p><b>7/20/06</b><br/> Teleconference<br/> 1:00 to 2:00 PM<br/> 1 Hour</p> | <ul style="list-style-type: none"> <li>• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings</li> </ul>  | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Jane Axelrad, CDER<br/> Ann Wion, OCC<br/> Malcolm Bertoni, OPPL<br/> Frank Claunts, OM<br/> Deborah Henderson, CDER</p>  |

|   |  |  |
|---|--|--|
|   |  | <p>Ralph Lillie, CDER<br/> Nancy Boocker, CDER<br/> Karen Meister, OL<br/> Patricia Stewart, OPPL<br/> Roger McClung, HHS</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Scott Lassman, PhRMA<br/> Lynne Tracey, Procter &amp; Gamble<br/> Sharon Olmstead, Schering Plough<br/> Bill Rosen, Pfizer<br/> Annetta Beauregard, Eli Lilly<br/> Bruce Burlington, Wyeth<br/> Peter Loupos, Sanofi-Aventis<br/> Tony Rogers, AstraZeneca</p> <p><b>BIO:</b><br/> Alison Lawton, Genzyme<br/> Kay Holcombe, Genzyme<br/> Roy Baranello, Wyeth<br/> Amit Sachdev, BIO<br/> Donna Peterson, Amgen<br/> Sara Radcliffe, BIO<br/> Bob Pietrusko, Millennium<br/> Andrew Emmett, BIO</p>   |
| <p><b>7/27/06</b><br/> 1:00 to 4:00 PM<br/> 3 Hours</p> | <ul style="list-style-type: none"> <li>• The inflation adjustor proposal</li> <li>• The workload adjustor proposal</li> <li>• Current status of CDER/CBER resources</li> <li>• Trademark review process proposal</li> <li>• Financial baseline and funding levels</li> </ul> | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Ann Wion, OCC<br/> Malcolm Bertoni, OPPL<br/> Frank Claunts, OM<br/> John Jenkins, CDER<br/> Robert Yetter, CBER<br/> Deborah Henderson, CDER<br/> Jane Axelrad, CDER<br/> Ralph Lillie, CDER<br/> Nancy Boocker, CDER<br/> Karen Meister, OL<br/> Martha Louviere, OM<br/> Jonathan Mathieu, OPPL<br/> Roger McClung, HHS<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Scott Lassman, PhRMA<br/> Lynne Tracey, Procter &amp; Gamble<br/> Sharon Olmstead, Schering Plough<br/> Bill Rosen, Pfizer<br/> Annetta Beauregard, Eli Lilly<br/> Bruce Burlington, Wyeth<br/> Peter Loupos, Sanofi-Aventis (tcon)<br/> Tony Rogers, AstraZeneca (tcon)<br/> Gretchen Dieck, Pfizer (tcon)<br/> Bob Lee, Eli Lilly (tcon)</p> <p><b>BIO:</b></p> |

|  |  |   |
|--|--|---|
|  |  | <p>Alison Lawton, Genzyme<br/> Kay Holcombe, Genzyme<br/> Roy Baranello, Wyeth (tcon)<br/> Amit Sachdev, BIO<br/> Donna Peterson, Amgen<br/> Sara Radcliffe, BIO<br/> Bob Pietrusko, Millennium (tcon)<br/> Andrew Emmett, BIO</p>  |
| <p><b>8/3/06</b><br/> Teleconference<br/> 1:00 to 2:00 PM<br/> 1 Hour</p>  | <ul style="list-style-type: none"> <li>Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings</li> </ul> | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Ann Wion, OCC<br/> Malcolm Bertoni, OPPL<br/> Frank Claunts, OM<br/> Robert Yetter, CBER<br/> Martha Louviere, OM<br/> Deborah Henderson, CDER<br/> Jane Axelrad, CDER<br/> Ralph Lillie, CDER<br/> Nancy Boocker, CDER<br/> Karen Meister, OL<br/> Roger McClung, HHS<br/> Howard Chazin, CDER<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Tricia de Santis, Johnson and Johnson<br/> Bill Rosen, Pfizer<br/> Annetta Beauregard, Eli Lilly<br/> Peter Loupos, Sanofi-Aventis<br/> Gretchen Dieck, Pfizer<br/> Tony Rogers, AstraZeneca</p> <p><b>BIO:</b><br/> Alison Lawton, Genzyme<br/> Kay Holcombe, Genzyme<br/> Roy Baranello, Wyeth<br/> Amit Sachdev, BIO<br/> Donna Peterson, Amgen<br/> Sara Radcliffe, BIO<br/> Andrew Emmett, BIO</p> |
| <p><b>8/10/06</b><br/> Teleconference<br/> 1:00 to 2:00 PM<br/> 1 Hour</p> | <ul style="list-style-type: none"> <li>Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings</li> </ul> | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Ann Wion, OCC<br/> Malcolm Bertoni, OPPL<br/> Frank Claunts, OM<br/> John Jenkins, CDER<br/> Martha Louviere, OM<br/> Ralph Lillie, CDER<br/> Jane Axelrad, CDER<br/> Nancy Boocker, CDER<br/> Roger McClung, HHS<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b></p>  |

|  |   |   |
|--|---|---|
|  |   | <p>Alan Goldhammer, PhRMA<br/> Bruce Burlington, Wyeth<br/> Bill Rosen, Pfizer<br/> Annetta Beauregard, Eli Lilly<br/> Peter Loupos, Sanofi-Aventis<br/> Gretchen Dieck, Pfizer<br/> Tony Rogers, AstraZeneca<br/> Scott Lassman, PhRMA</p> <p><b>BIO:</b><br/> Alison Lawton, Genzyme<br/> Sara Radcliffe, BIO<br/> Donna Peterson, Amgen<br/> Andrew Emmett, BIO</p>  |
| <p><b>8/24/06</b><br/> Teleconference<br/> 1:00 to 2:00 PM<br/> 1 Hour</p> | <ul style="list-style-type: none"> <li>• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings</li> <li>• Next steps in FDA compliance with Public Accountability requirement for PDUFA reauthorization</li> </ul> | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Ann Wion, OCC<br/> Malcolm Bertoni, OPPL<br/> Frank Claunts, OM<br/> John Jenkins, CDER<br/> Robert Yetter, CBER<br/> Ralph Lillie, CDER<br/> Jane Axelrad, CDER<br/> Nancy Boocker, CDER<br/> Roger McClung, HHS<br/> Karen Meister, OL<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Tricia de Santis, Johnson &amp; Johnson<br/> Lynne Tracey, Proctor &amp; Gamble<br/> Scott Lassman, PhRMA<br/> Peter Loupos, Sanofi-Aventis</p> <p><b>BIO:</b><br/> Bob Pietrusko, Millenium<br/> Amit Sachdev, BIO<br/> Roy Baranello, Wyeth<br/> Sara Radcliffe, BIO<br/> Kaye Holcolme, Genzyme<br/> Andrew Emmett, BIO</p> |
| <p><b>8/31/06</b> Teleconference<br/> 1:00 to 2:00 PM<br/> 1 Hour</p>      | <ul style="list-style-type: none"> <li>• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings</li> </ul>  | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Frank Claunts, OM<br/> Malcolm Bertoni, OPPL<br/> Martha Louviere, OM<br/> Robert Yetter, CBER<br/> Deborah Henderson, CDER<br/> Ralph Lillie, CDER<br/> Jane Axelrad, CDER<br/> Nancy Boocker, CDER<br/> Roger McClung, HHS<br/> Karen Meister, OL<br/> Patricia Stewart, OPPL</p>   |

|  |  |  |
|--|--|--|
|  |  | <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Tricia de Santis, Johnson &amp; Johnson<br/> Bruce Burlington, Wyeth<br/> Sharon Olmstead, Schering Plough<br/> Lynne Tracey, Proctor &amp; Gamble<br/> Scott Lassman, PhRMA<br/> Peter Loupos, Sanofi-Aventis<br/> Bill Rosen, Pfizer<br/> Annette Beauregard, Eli Lilly</p> <p><b>BIO:</b><br/> Bob Pietrusko, Millenium<br/> Amit Sachdev, BIO<br/> Roy Baranello, Wyeth<br/> Sara Radcliffe, BIO<br/> Kaye Holcolme, Genzyme</p>   |
| <p><b>9/7/06</b><br/> 1:00 to 5:00 PM<br/> 4 Hours</p> | <ul style="list-style-type: none"> <li>• Discussion of proposed inflation adjustor and workload adjustor with a complexity factor</li> <li>• Discussion of method for calculating the proposed PDUFA financial baseline in FY 2008.</li> <li>• Discuss FDA proposal for 9 technical fixes</li> </ul> | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Frank Claunts, OM<br/> Ann Wion, OCC<br/> Malcolm Bertoni, OPPL<br/> John Jenkins, CDER<br/> Robert Yetter, CBER<br/> Deborah Henderson, CDER<br/> Martha Louviere, OM<br/> Ralph Lillie, CDER<br/> Jane Axelrad, CDER<br/> Nancy Boocker, CDER<br/> Michael Jones, CDER (tcon)<br/> Karen Meister, OL<br/> Roger McClung, HHS<br/> Jonathan Mathieu, OPPL<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Tricia de Santis, Johnson &amp; Johnson<br/> Bruce Burlington, Wyeth<br/> Sharon Olmstead, Schering Plough<br/> Scott Lassman, PhRMA<br/> Bill Rosen, Pfizer<br/> Peter Loupos, Sanofi-Aventis<br/> Tony Rogers, AztraZeneca<br/> Annette Beauregard, Eli Lilly<br/> Chin Koerner, Novartis<br/> Edward Tripp, Abbot<br/> Lynne Tracey, Proctor &amp; Gamble (tcon)</p> <p><b>BIO:</b><br/> Bob Pietrusko, Millenium<br/> Amit Sachdev, BIO<br/> Roy Baranello, Wyeth<br/> Sara Radcliffe, BIO<br/> Kay Holcombe, Genzyme<br/> Andrew Emmett, BIO</p> |

|  |  |   |
|--|--|---|
|  |  | Alison Lawton, Genzyme<br>Donna Peterson, Amgen   |
| <b>9/8/06</b><br>1:00 to 5:00 PM<br>4 Hours    | <ul style="list-style-type: none"> <li>• Discussion of proposed inflation adjustor and workload adjustor with a complexity factor</li> <li>• Discussion of method for calculating the proposed PDUFA financial baseline in FY 2008.</li> <li>• Discuss safety program proposal</li> <li>• Discuss electronic review environment proposal</li> <li>• Discussion of proposal for timelines for labeling and post marketing commitment (PMC) discussions</li> </ul> | <b>FDA:</b><br>Theresa Mullin, OPPL<br>Frank Claunts, OM<br>Ann Wion, OCC<br>Malcolm Bertoni, OPPL<br>John Jenkins, CDER<br>Robert Yetter, CBER<br>Deborah Henderson, CDER<br>Martha Louviere, OM<br>Ralph Lillie, CDER<br>Jane Axelrad, CDER<br>Nancy Boocker, CDER<br>Michael Jones, CDER (tcon)<br>Karen Meister, OL<br>Roger McClung, HHS (tcon)<br>Howard Chazin, CDER<br>Patricia Stewart, OPPL<br><br><b>PhRMA:</b><br>Alan Goldhammer, PhRMA<br>Tricia de Santis, Johnson & Johnson<br>Bruce Burlington, Wyeth<br>Sharon Olmstead, Schering Plough<br>Scott Lassman, PhRMA<br>Gretchen Dieck, Pfizer (tcon)<br>Peter Loupos, Sanofi-Aventis<br>Bill Rosen, Pfizer<br>Annette Beauregard, Eli Lilly<br>Tony Rogers, AztraZeneca<br>Edward Tripp, Abbot<br>Chin Koerner, Novartis<br>Lynne Tracey, Proctor & Gamble (tcon)<br><br><b>BIO:</b><br>Bob Pietrusko, Millenium<br>Amit Sachdev, BIO<br>Roy Baranello, Wyeth<br>Sara Radcliffe, BIO<br>Kay Holcombe, Genzyme<br>Andrew Emmett, BIO<br>Donna Peterson, Amgen |
| <b>9/21/06</b><br>1:00 to 3:30 PM<br>2 ½ Hours | <ul style="list-style-type: none"> <li>• Continued discussion of proposed enhancements for PDUFA IV</li> <li>• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings</li> </ul>   | <b>FDA:</b><br>Theresa Mullin, OPPL<br>Frank Claunts, OM<br>Ann Wion, OCC<br>Malcolm Bertoni, OPPL<br>John Jenkins, CDER<br>Robert Yetter, CBER<br>Deborah Henderson, CDER<br>Martha Louviere, OM<br>Jane Axelrad, CDER<br>Nancy Boocker, CDER<br>Karen Meister, OL   |

|  |   |   |
|--|---|---|
|  |   | <p>Michael Jones, CDER (tcon)<br/> Roger McClung, HHS (tcon)<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Bruce Burlington, Wyeth<br/> Gretchen Dieck, Pfizer (tcon)<br/> Bill Rosen, Pfizer<br/> Scott Lassman, PhRMA (tcon)<br/> Tony Rogers, AztraZeneca<br/> Peter Loupos, Sanofi-Aventis (tcon)<br/> Annette Beauregard, Eli Lilly (tcon)<br/> Tricia de Santis, Johnson &amp; Johnson (tcon)<br/> Sharon Olmstead, Schering Plough (tcon)<br/> Lynne Tracey, Proctor &amp; Gamble (tcon)</p> <p><b>BIO:</b><br/> Bob Pietrusko, Millenium<br/> Amit Sachdev, BIO<br/> Roy Baranello, Wyeth<br/> Sara Radcliffe, BIO<br/> Kay Holcombe, Genzyme<br/> Andrew Emmett, BIO<br/> Alison Lawton, Genzyme<br/> Donna Peterson, Amgen (tcon)</p> |
| <p><b>10/5/06</b><br/> 9:00 to 11:00 AM<br/> 2 Hours</p> | <ul style="list-style-type: none"> <li>• Direct to consumer advertising review proposal</li> <li>• Sound financial footing proposals</li> <li>• Proposed resource requirements</li> <li>• Implementation of Good review Management Principles (GRMPs)</li> <li>• Proprietary name review</li> </ul> | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Frank Claunts, OM<br/> Ann Wion, OCC<br/> Malcolm Bertoni, OPPL<br/> John Jenkins, CDER<br/> Robert Yetter, CBER<br/> Deborah Henderson, CDER<br/> Martha Louviere, OM<br/> Ralph Lillie, CDER<br/> Jane Axelrad, CDER<br/> Michael Jones, CDER (tcon)<br/> Roger McClung, HHS<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Bruce Burlington, Wyeth<br/> Scott Lassman, PhRMA<br/> Gretchen Dieck, Pfizer<br/> Bill Rosen, Pfizer<br/> Tony Rogers, AztraZeneca (tcon)<br/> Annette Beauregard, Eli Lilly<br/> Tricia de Santis, Johnson &amp; Johnson (tcon)<br/> Sharon Olmstead, Schering Plough<br/> Lynne Tracey, Proctor &amp; Gamble (tcon)</p>   |

|   |   |  |
|---|---|--|
|   |   | <p><b>BIO:</b><br/> Bob Pietrusko, Millenium<br/> Amit Sachdev, BIO<br/> Roy Baranello, Wyeth<br/> Sara Radcliffe, BIO<br/> Kay Holcombe, Genzyme<br/> Andrew Emmett, BIO<br/> Alison Lawton, Genzyme<br/> Donna Peterson, Amgen (tcon)</p>  |
| <p><b>10/12/06</b><br/> Teleconference<br/> 1:00 to 1:30 PM<br/> ½ Hour</p> | <ul style="list-style-type: none"> <li>• Workload adjustor complexity factor</li> <li>• Expedited drug development guidances</li> <li>• GRMP implementation proposal</li> <li>• Direct to consumer advertising (DTCA) proposal</li> <li>• Discuss proposal to eliminate the legislative language that restricts using PDUFA funds to the peri-approval period of 2-3 years post approval</li> </ul> | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Frank Claunts, OM<br/> Ann Wion, OCC<br/> Malcolm Bertoni, OPPL<br/> John Jenkins, CDER<br/> Robert Yetter, CBER<br/> Deborah Henderson, CDER<br/> Howard Chazin, CDER<br/> Ralph Lillie, CDER<br/> Jane Axelrad, CDER<br/> Michael Jones, CDER<br/> Nancy Boocker, CDER<br/> Karen Meister, OL<br/> Patricia Stewart, OPPL</p> <p><b>PhRMA:</b><br/> Alan Goldhammer, PhRMA<br/> Tricia de Santis, Johnson &amp; Johnson<br/> Petr Loupos, Sanofi-Aventis<br/> Sharon Olmstead, Schering Plough<br/> Lynne Tracey, Proctor &amp; Gamble<br/> Scott Lassman, PhRMA<br/> Bill Rosen, Pfizer<br/> Gretchen Dieck, Pfizer<br/> Annette Beauregard, Eli Lilly<br/> Tony Rogers, AztraZeneca</p> <p><b>BIO:</b><br/> Bob Pietrusko, Millenium<br/> Amit Sachdev, BIO<br/> Donna Peterson, Amgen<br/> Sara Radcliffe, BIO<br/> Kay Holcombe, Genzyme<br/> Andrew Emmett, BIO</p> |
| <p><b>11/2/06</b><br/> 1:00 to 4:00 PM<br/> 3 Hours</p>                     | <ul style="list-style-type: none"> <li>• Discuss proposed changes to the commitment letter</li> <li>• Discuss proposed changes to legislative language</li> </ul>   | <p><b>FDA:</b><br/> Theresa Mullin, OPPL<br/> Frank Claunts, OM<br/> Ann Wion, OCC<br/> Martie Louviere, OM<br/> John Jenkins, CDER<br/> Mark Gray, OM<br/> Deborah Henderson, CDER<br/> Jane Axelrad, CDER<br/> Ralph Lillie, CDER<br/> Michael Jones, CDER</p>   |

|  |  |   |
|--|--|---|
|  |  | <p>Nancy Boocker, CDER<br/>Michael Sauers, HHS<br/>Ann Sullivan, OPPL<br/>Robert Yetter, CBER</p> <p><b>PhRMA:</b><br/>Alan Goldhammer, PhRMA<br/>Bruce Burlington, Wyeth<br/>Scott Lassman, PhRMA<br/>Gretchen Dieck, Pfizer<br/>Tony Rogers, AstraZeneca<br/>Annetta Beauregard, Eli Lilly<br/>Lynne Tracey, Procter &amp; Gamble<br/>Tricia de Santis, Johnson and Johnson<br/>Peter Loupos, Sanofi-Aventis<br/>Bill Rosen, Pfizer</p> <p><b>BIO:</b><br/>Amit Sachdev, BIO<br/>Donna Peterson, Amgen<br/>Sara Radcliffe, BIO<br/>Kay Holcombe, Genzyme<br/>Andrew Emmett, BIO<br/>Alison Lawton, Genzyme<br/>Roy Baranello, Wyeth</p> |
|--|--|---|