

**Table 4. PDUFA IV Meetings – Technical Discussions
with Regulated Industry Postmarketing Safety
Subgroup**

Date Time Length	Subjects	Participants
<p>March 29, 2006 10:00 a.m. – Noon 2 hours</p>	<p>Agree to issues that the subgroup will consider and some initial timelines for deliverables</p>	<p>FDA: Debbie.Henderson, CDER Miles Braun, CBER Ralph Lillie, CDER Heidi Gertner, OCC Julie Beitz, CDER Anne Henig, CDER</p> <p>PhRMA: Alan Goldhammer, PhRMA Jim Kotsanos, Eli Lilly Scott Lassman, PhRMA Gretchen Dieck, Pfizer Dave Pizzuti, Johnson & Johnson Bob Lee, Eli Lilly Ron Garutti, Schering Plough</p> <p>BIO: Andrew Emmett, BIO Kay Holcombe, Genzyme Sara Radcliffe, BIO Bob Pietrusko, Millennium Phil Noguchi, Amgen</p>
<p>April 6, 2006 10:00 a.m. – Noon 2 hours</p>	<p>Presentation of FDA's proposal on how to enhance PDUFA-funded surveillance capacity.</p>	<p>FDA: Debbie.Henderson, CDER Miles Braun, CBER Ralph Lillie, CDER Judy Staffa, CDER Julie Beitz, CDER Cindy Kortepeter, CDER Anne Henig, CDER Heidi Gertner, OCC</p> <p>PhRMA: Alan Goldhammer, PhRMA Jim Kotsanos, Eli Lilly Scott Lassman, PhRMA Gretchen Dieck, Pfizer Dave Pizzuti, Johnson & Johnson</p> <p>BIO: Andrew Emmett, BIO Joanna Haas, Genzyme Sara Radcliffe, BIO Kay Holcombe, Genzyme Bob Pietrusko, Millennium Phil Noguchi, Amgen</p>

<p>April 20, 2006 10:00 a.m. – Noon 2 hours</p>	<p>Presentation of FDA's proposals: Epidemiology Methods and Best Practices and Risk Minimization Plans</p>	<p>FDA: Debbie.Henderson, CDER Miles Braun, CBER Ralph Lillie, CDER Judy Staffa, CDER Julie Beitz, CDER Claudia Karwoski, CDER Carol Holquist, CDER Anne Henig, CDER Heidi Gertner OCC</p> <p>PhRMA: Alan Goldhammer, PhRMA Jim Kotsanos, Eli Lilly Scott Lassman, PhRMA Gretchen Dieck, Pfizer</p> <p>BIO: Andrew Emmett, BIO Kay Holcombe, Genzyme Sara Radcliffe, BIO Bob Pietrusko, Millennium</p>
<p>May 4, 2006 10:00 a.m. – 1:00 p.m. 3 hours</p>	<p>Trademark Proposals</p>	<p>FDA: Debbie Henderson, CDER Judy Staffa, CDER Ralph Lillie, CDER Denise Toyer, CDER Julie Beitz, CDER Maryann Gallagher, CBER Carol Holquist, CDER Jane Axelrad, CDER Anne Henig, CDER</p> <p>PhRMA: Steve Hartman, Novartis Bob Lee, Lilly Doug Doban, Astra-Zeneca Scott Lassman, PhRMA Kathy Gans-Brangs, Astra-Zeneca</p> <p>BIO: Andrew Emmett, BIO Kay Holcombe, Genzyme Sara Radcliffe, BIO Bob Pietrusko, Millennium</p>
<p>May 18, 2006 10:00 a.m. – Noon 2 hours</p>	<p>Resources needed for post marketing surveillance</p>	<p>FDA: Debbie Henderson, CDER Julie Beitz, CDER Ralph Lillie, CDER Judy Staffa, CDER Bob Ball, CBER Carol Holquist, CDER Heidi Gertner, OCC Anne Henig, CDER David Horowitz</p>

		<p>PhRMA: Alan Goldhammer, PhRMA Gretchen Dieck, Pfizer Dave Pizzuti, Johnson & Johnson</p> <p>BIO: Andrew Emmett, BIO Sara Radcliffe, BIO</p>
June 1, 2006 10:00 a.m. – Noon 2 hours	Follow up to resource discussion. OSE presentation on vision for postmarket surveillance and epidemiology	<p>FDA: Debbie Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER Gerald DalPan, CDER Bob Ball, CBER Judy Staffa, CDER</p> <p>PhRMA: Alan Goldhammer, PhRMA Jim Kotsanos, Lilly Scott Lassman, PhRMA Linda Carter, Johnson and Johnson Gretchen Dieck, Pfizer</p> <p>BIO: Andrew Emmett, BIO Bob Pietrusko, Millenium Sara Radcliffe, BIO Kay Holcombe, Genzyme</p>
June 19, 2006 T-con between FDA and Industry 1:30 – 2:30 p.m. 1 hour	Steps needed to move forward	<p>FDA: Debbie Henderson, CDER Ralph Lillie, CDER</p> <p>PhRMA: Alan Goldhammer, PhRMA Jim Kotsanos, Lilly Scott Lassman, PhRMA Gretchen Dieck, Pfizer</p> <p>BIO: Bob Pietrusko, Millenium</p>
June 29, 2006 10:00 a.m. – 1:00 p.m. 3 hours	Tradename Discussion	<p>FDA: Debbie Henderson, CDER Carol Holquist, CDER Ralph Lillie, CDER Anne Henig, CDER</p> <p>PhRMA: Bob Lee, Lilly Kathy Gans-Brangs, Astra-Zeneca Steve Hartman, Novartis Scott Lassman, PhRMA</p> <p>BIO: Kay Holcombe, Genzyme</p>

		Bob Pietrusko, Millenium
July 5, 2006 T-con between FDA and Industry 8:00 – 9:00 a.m. 1 hour	Finalize Tradename Proposal	<p>FDA: Debbie Henderson, CDER Judy Staffa, CDER Ralph Lillie, CDER Heidi Gertner, OCC Carol Holquist, CDER Anne Henig, CDER Bob Sausville, CBER</p> <p>PhRMA: Alan Goldhammer, PhRMA Kathy Gans-Brangs, Astra-Zeneca Scott Lassman, PhRMA Steve Hartman, Novartis Gretchen Dieck, Pfizer Bob Lee, Lilly Jim Kotsanos, Lilly</p> <p>BIO: Bob Pietrusko, Millenium Kay Holcombe, Genzyme Andrew Emmett, BIO Sara Radcliffe, BIO</p>
July 6, 2006 9:00 – 11:00 a.m. 2 hours	Tradename Proposal	<p>FDA: Debbie Henderson, CDER Judy Staffa, CDER Ralph Lillie, CDER Heidi Gertner, OCC Anne Henig, CDER</p> <p>PhRMA: Alan Goldhammer, PhRMA Gretchen Dieck, Pfizer Scott Lassman, PhRMA Jim Kotsanos, Lilly</p> <p>BIO: Bob Pietrusko, Millenium Kay Holcombe, Genzyme Andrew Emmett, BIO Sara Radcliffe, BIO</p>
July 11, 2006 T-con between FDA and Industry 8:00 – 9:00 a.m.	Further discussion on Trademark Proposal	<p>FDA: Debbie.Henderson, CDER Ralph Lillie, CDER Heidi Gertner, OCC Anne Henig, CDER Carol Holquist, CDER Julie Beitz, CDER Maryann Gallagher, CBER Bob Sausville, CBER</p> <p>PhRMA: Alan Goldhammer, PhRMA Bob Lee, Lilly</p>

		<p>Steve Hartman, Novartis Kathy Gans-Brangs, Astra-Zeneca</p> <p>BIO: Bob Pietrusko, Millenium Kay Holcombe, Genzyme Sra Radcliffe, BIO</p>
<p>July 24, 2006 T-con between FDA and Industry 11:00 a.m. – Noon 1 hour</p>	<p>Status of PDUFA document development</p>	<p>FDA: Debbie Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER</p> <p>PhRMA: Alan Goldhammer, PhRMA Jim Kotsanos, Lilly Gretchen Dieck, Pfizer</p> <p>BIO: Bob Pietrusko, Millenium</p>
<p>July 25, 2006 T-con between FDA and Industry 8:00 – 9:00 a.m. 1 hour</p>	<p>PDUFA Trademark Discussion</p>	<p>FDA: Debbie Henderson, CDER Carol Holquist, CDER Ralph Lillie, CDER Anne Henig, CDER Denise Toyer, CDER Ele Pratt, CBER Maryann Gallagher, CBER Julie Beitz, CDER Heidi Gertner, OCC</p> <p>PhRMA: Alan Goldhammer, PhRMA Scott Lassman, PhRMA Bob Lee, Lilly Kathy Gans-Brangs, Astra-Zeneca</p> <p>BIO: Kay Holcombe, Genzyme Bob Pietrusko, Millenium</p>
<p>July 27, 2006 9:30 – 11:30 a.m. 2 hours</p>	<p>Trademark Review Proposal</p>	<p>FDA: Debbie Henderson, CDER Ralph Lillie, CDER Anne Henig, CDER Mary Willy, CDER Heidi Gertner, OCC</p> <p>PhRMA: Alan Goldhammer, PhRMA Gretchen Dieck, Pfizer Jim Kotsanos, Lilly</p> <p>BIO: Kay Holcombe, Genzyme Andrew Emmett, BIO Sara Radcliffe, BIO</p>

<p>August 3, 2006 10:00 a.m. – Noon 2 hours</p>	<p>Review of draft proposal</p>	<p>FDA: Debbie Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER Heidi Gertner, OCC</p> <p>PhRMA: Jim Kotsanos, Lilly Scott Lassman, PhRMA, Alan Goldhammer, PhRMA Gretchen Dieck, Pfizer</p> <p>BIO: Andrew Emmett, BIO Kay Holcombe, Genzyme Sara Radcliffe, BIO</p>
<p>August 24, 2006 10:00 a.m. – Noon 2 hours</p>	<p>Discussion of the Enhancement and Modernization of the FDA Drug Safety System document</p>	<p>FDA: Debbie Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER Judy Staffa, CDER Julie Beitz, CDER Heidi Gertner, OCC Cindy Kortepeter, CDER Bob Ball, CBER Min Chen, CDER</p> <p>PhRMA: Alan Goldhammer, PhRMA Jim Kotsanos, Lilly Scott Lassman, PhRMA, Gretchen Dieck, Pfizer</p> <p>BIO: Andrew Emmett, BIO Sara Radcliffe, BIO Kay Holcombe, Genzyme Bob Pietrusko, Millenium</p>
<p>August 31, 2006 10:00 a.m. – Noon 2 hours</p>	<p>Discussion of the Enhancement and Modernization of the FDA Drug Safety System document</p>	<p>FDA: Debbie Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER Judy Staffa, CDER Julie Beitz, CDER Miles Braun CBER</p> <p>PhRMA: Alan Goldhammer, PhRMA Jim Kotsanos, Lilly Scott Lassman, PhRMA</p> <p>BIO: Bob Pietrusko, Millenium Sara Radcliffe, BIO Kay Holcombe, Genzyme</p>

<p>September 7, 2006 T-con between FDA and Industry 9:00 – 10:00 a.m. 1 hour</p>	<p>Discussion of the Enhancement and Modernization of the FDA Drug Safety System document</p>	<p>FDA: Debbie Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER Judy Staffa, CDER Julie Beitz, CDER Miles Braun, CBER</p> <p>PhRMA: Alan Goldhammer, PhRMA Gretchen Dieck, Pfizer Scott Lassman, PhRMA</p> <p>BIO: Bob Pietrusko, Millenium Andrew Emmett, BIO Sara Radcliffe, BIO Kay Holcombe, Genzyme</p>
<p>October 12, 2006 T-con between FDA and Industry 9:00 – 11:00 p.m. 2 hours</p>	<p>Discuss current goals letter and interface with IOM report</p>	<p>FDA: Debbie Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER Judy Staffa, CDER Julie Beitz, CDER Heidi Gertner, OCC</p> <p>PhRMA: Alan Goldhammer, PhRMA Gretchen Dieck, Pfizer Scott Lassman, PhRMA Jim Kotsanos, Lilly</p> <p>BIO: Bob Pietrusko, Millenium Andrew Emmett, BIO Sara Radcliffe, BIO</p>