Toxicological Research							

* One meeting was held with 2 sessions - Session A (a product specific meeting) and Session B (a particular matter of general applicability meeting)

PRESCRIPTION DRUG USER FEE ACT

Mr. Hinchey: 8. Please provide for the record detailed information on meetings by FDA staff with members of regulated industry regarding the agency's proposal for reauthorization of the Prescription Drug User Fee Act. Please include for each meeting: dates and times of meetings, lengths of meetings, the subject of each meeting, and meeting participants.

Response: I will be glad to provide that information.
The information follows in documents including the FDA-industry Steering Group (table 1), Financial subgroup (table 2), Premarket subgroup (table3), postmarket subgroup (table 4) IT/IM subgroup (table 5) and the DTC advertising subgroup (table 6). [The information follows:]

Table 1. FDA Industry Steering Group Meetings

Date Time Length	Subjects	Participants
10/25/05 4:00 to 5:00 PM 1 Hour	• Upcoming PDUFA IV reauthorization • PDUFA IV technical discussion steering group and technical groups • Schedule of technical discussions • Data on PDUFA trends • Public accountability/Consultation on reauthorization	**FDA:** Theresa Mullin, OPPL Jane Axelrad, CDER (phone) Frank Claunts, OM Bob Yetter, CBER John Jenkins, CDER Malcolm Bertoni, OPPL Mark Gray, OCIO Fred Farmer, OCIO Paul Seligman, CDER (phone) Patricia Stewart, OPPL Ralph Lillie, CDER Ann Sullivan, OPPL David Horowitz, ORA **PhRMA/BIO:** Roy Baranello, Wyeth Andrew Emmett, BIO Donna Peterson, Amgen Alan Goldhammer, PhRMA

Date Time Length	Subjects	Participants
		Bob Pietrusko, Millennium Rachel Carle, Genzyme phone) Scott Lassman, PhRMA Bruce Burlington, Wyeth Stacey Holdsworth, Eli Lilly Bill Rosen, Pfizer Lynne Tracey, Procter and Gamble Sharon Olmstead, Schering-Plough Kay Holcombe, Consultant to BIO Peter Loupos, Sanofi-Aventis (phone)
1/24/06 3:00 to 4:30 PM 1 ½ Hours	• FDA responses to the industry's data request in preparation for the upcoming PDUFA IV reauthorization.	**FDA:** Theresa Mullin, OPPL Jane Axelrad, CDER Frank Claunts, OM Leonard Wilson, CBER John Jenkins, CDER Malcolm Bertoni, OPPL Ann Wion, OCC Fred Farmer, OCIO Deborah Henderson, CDER Robert Temple, CDER Ralph Lillie, CDER Nancy Boocker, CDER Michael Lanthier, CDER Patricia Stewart, OPPL **PhRMA** Alan Goldhammer, PhRMA Stacey Holdsworth, Eli Lilly Scott Lassman, PhRMA Jim Kotsanos, Eli Lilly Bill Rosen, Pfizer Gretchen Dieck, Pfizer Bruce Burlington, Wyeth Peter Loupos, Sanofi-Aventis

Date Time Length	Subjects	Participants
		Sharon Olmstead, Schering Plough Lynne Tracey, Procter & Gamble Don Sauer, Wyeth Steve Tilton, PhRMA **BIO:** Alison Lawton, Genzyme Corporation Roy Baranello, Wyeth Donna Peterson, Amgen Bob Pietrusko, Millennium Sara Radcliffe, BIO Andrew Emmett, BIO
2/14/06 Teleconference 3:00 to 4:00 PM 1 Hour	• Discuss industry request for data on PDUFA program and postmarket safety	**FDA:** Theresa Mullin, OPPL Jane Axelrad, CDER Deborah Henderson, CDER Ralph Lillie, CDER Patricia Stewart, OPPL **Industry:** Alan Goldhammer, PhRMA Sara Radcliffe, PhRMA Donna Peterson, BIO Andrew Emmett, BIO
3/16/06 1:00 to 4:00 PM 3 Hours	• Discuss FDA versus industry perspectives on PDUFA reauthorization. • The meeting concluded with agreement to hold more detailed discussions of specific issues in subsequent meetings of technical subgroups.	**FDA:** Theresa Mullin, OPPL Jane Axelrad, CDER Ann Wion, OCC Robert Yetter, CBER John Jenkins, CDER Malcolm Bertoni, OPPL Martha Louviere, OM Fred Farmer, OCIO Deborah Henderson, CDER David Horowitz, ORA Ralph Lillie, CDER Nancy Boocker, CDER John Gentile, OM Karen Meister, OL Patricia Stewart, OPPL

Date Time Length	Subjects	Participants
		PhRMA Alan Goldhammer, PhRMA Tricia de Santis, Johnson and Johnson Lynne Tracey, Procter & Gamble Sharon Olmstead, Schering Plough Bill Rosen, Pfizer Peter Loupos, Sanofi-Aventis Bruce Burlington, Wyeth Tony Rogers, AstraZeneca Scott Lassman, PhRMA Don Sauer, Wyeth Annetta Beauregard, Eli Lilly **BIO:** Alison Lawton, Genzyme Kay Holcome, Genzyme Roy Baranello, Wyeth Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO Bob Pietrusko, Millennium Andrew Emmett, BIO
3/30/06 Teleconference 3:00 to 4:00 PM 1 Hour	• Status of subgroup activities and identification of issues for discussion at future Steering Group meetings. • 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.	**FDA:** Theresa Mullin, OPPL Jane Axelrad, CDER Ann Wion, OCC Robert Yetter, CBER John Jenkins, CDER Malcolm Bertoni, OPPL Martha Louviere, OM Fred Farmer, OCIO Deborah Henderson, CDER Nancy Boocker, CDER Ralph Lillie, CDER Roger McClung, HHS Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA

Date Time Length	Subjects	Participants
		Tricia de Santis, Johnson and Johnson Lynne Tracey, Procter & Gamble Sharon Olmstead, Schering Plough Bill Rosen, Pfizer Peter Loupos, Sanofi-Aventis Bruce Burlington, Wyeth Gretchen Dieck, Pfizer Tony Rogers, AstraZeneca Don Sauer, Wyeth Scott Lassman, PhRMA Annetta Beauregard, Eli Lilly **BIO:** Alison Lawton, Genzyme Kay Holcombe, Genzyme Roy Baranello, Wyeth Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO Bob Pietrusko, Millennium Andrew Emmett, BIO
4/27/06 1:00 to 4:00 PM 3 Hours	• FDA funding, costs and efficiencies • Quality of application submissions • FDA workload and productivity	**FDA** Theresa Mullin, OPPL Jane Axelrad, CDER John Jenkins, CDER Malcolm Bertoni, OPPL Frank Claunts, OM Fred Farmer, OCIO Deborah Henderson, CDER Nancy Boocker, CDER Ralph Lillie, CDER Roger McClung, HHS Karen Meister, OL Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Lynne Tracey, Procter & Gamble Bruce Burlington, Wyeth

Date Time Length	Subjects	Participants
		Tony Rogers, AstraZeneca Annetta Beauregard, Eli Lilly Tricia de Santis, Johnson and Johnson (tcon) **BIO:** Alison Lawton, Genzyme Kay Holcombe, Genzyme Roy Baranello, Wyeth Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO Bob Pietrusko, Millennium Andrew Emmett, BIO
5/11/06 2:30 to 4:00 PM 1 ½ Hours	• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings	**FDA:** Theresa Mullin, OPPL John Jenkins, CDER Ann Wion, OCC Robert Yetter, CBER Frank Claunts, OM Malcolm Bertoni, OPPL Martha Louviere, OM Fred Farmer, OCIO Deborah Henderson, CDER Nancy Boocker, CDER Ralph Lillie, CDER Roger McClung, HHS Karen Meister, OL Howard Chazin, CDER Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Tricia de Santis, Johnson and Johnson Lynne Tracey, Procter & Gamble Sharon Olmstead, Schering Plough Bill Rosen, Pfizer Annetta Beauregard, Eli Lilly Bruce Burlington, Wyeth Gretchen Dieck, Pfizer Tony Rogers, AstraZeneca

Date Time Length	Subjects	Participants
		Don Sauer, Wyeth Scott Lassman, PhRMA **BIO:** Alison Lawton, Genzyme Kay Holcombe, Genzyme Roy Baranello, Wyeth Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO Bob Pietrusko, Millennium Andrew Emmett, BIO
5/25/06 1:00 to 3:00 PM 2 Hours	• 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 • Finance subgroup technical proposals • Premarket group technical proposals regarding meeting management process • Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings	**FDA:** Theresa Mullin, OPPL John Jenkins, CDER Ann Wion, OCC Robert Yetter, CBER Frank Claunts, OM Malcolm Bertoni, OPPL Martha Louviere, OM Fred Farmer, OCIO Deborah Henderson, CDER Nancy Boocker, CDER Ralph Lillie, CDER Michael Jones, CDER Karen Meister, OL Howard Chazin, CDER Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Tricia de Santis, Johnson and Johnson Lynne Tracey, Procter & Gamble Sharon Olmstead, Schering Plough Bill Rosen, Pfizer Annetta Beauregard, Eli Lilly Bruce Burlington, Wyeth

Date Time Length	Subjects	Participants
		Gretchen Dieck, Pfizer Tony Rogers, AstraZeneca Don Sauer, Wyeth Scott Lassman, PhRMA **BIO:** Alison Lawton, Genzyme Kay Holcombe, Genzyme Roy Baranello, Wyeth Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO Bob Pietrusko, Millennium Andrew Emmett, BIO
6/22/06 1:00 to 4:00 PM 3 Hours	• Premarket subgroup proposals for meeting management goals • CMA pilots • The Inflation Adjustor proposal • The model for the financial baseline for FY 2008 • Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings	**FDA:** Theresa Mullin, OPPL John Jenkins, CDER (tcon) Ann Wion, OCC Robert Yetter, CBER Frank Claunts, OM Malcolm Bertoni, OPPL Martha Louviere, OM Jane Axelrad, CDER Deborah Henderson, CDER Nancy Boocker, CDER Howard Chazin, CDER Roger McClung, HHS Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Tricia de Santis, Johnson and Johnson Lynne Tracey, Procter & Gamble Sharon Olmstead, Schering Plough Bill Rosen, Pfizer Tony Rogers, AstraZeneca Bruce Burlington, Wyeth Scott Lassman, PhRMA **BIO:**

Date Time Length	Subjects	Participants
		Alison Lawton, Genzyme Kay Holcombe, Genzyme Roy Baranello, Wyeth Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO Bob Pietrusko, Millennium Andrew Emmett, BIO
7/6/06 Teleconference 1:00 to 2:30 PM 1 ½ Hours	• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings • Discussion of trends in appropriations for drug review	**FDA:** Theresa Mullin, OPPL Robert Yetter, CBER Ann Wion, OCC Malcolm Bertoni, OPPL Jane Axelrad, CDER Martha Louviere, OM Deborah Henderson, CDER Nancy Boocker, CDER Ralph Lillie, CDER Howard Chazin, CDER Roger McClung, HHS Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Tricia de Santis, Johnson and Johnson Bill Rosen, Pfizer Annetta Beauregard, Eli Lilly Bruce Burlington, Wyeth Gretchen Dieck, Pfizer Tony Rogers, AstraZeneca Don Sauer, Wyeth Scott Lassman, PhRMA Peter Loupos, Sanofi-Aventis **BIO:** Alison Lawton, Genzyme Kay Holcombe, Genzyme Roy Baranello, Wyeth Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO

Date Time Length	Subjects	Participants
		Bob Pietrusko, Millennium Andrew Emmett, BIO
7/13/06 Teleconference 1:00 to 2:00 PM 1 Hour	• IT Communications and Technical Interactions proposal • Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings	**FDA:** Theresa Mullin, OPPL Robert Yetter, CBER Ann Wion, OCC Malcolm Bertoni, OPPL John Jenkins, CDER Frank Claunts, OM Deborah Henderson, CDER Martha Louviere, OM Ralph Lillie, CDER Nancy Boocker, CDER Karen Meister, OL Margo Burnette, OCIO Roger McClung, HHS Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Tricia de Santis, Johnson and Johnson Lynne Tracey, Procter & Gamble Sharon Olmstead, Schering Plough Bill Rosen, Pfizer Annetta Beauregard, Eli Lilly Bruce Burlington, Wyeth Gretchen Dieck, Pfizer Tony Rogers, AstraZeneca Peter Loupos, Sanofi-Aventis Scott Lassman, PhRMA **BIO:** Alison Lawton, Genzyme Kay Holcombe, Genzyme Roy Baranello, Wyeth Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO Andrew Emmett, BIO
7/20/06	• Status of subgroup	**FDA:**

Date Time Length	Subjects	Participants
Teleconference 1:00 to 2:00 PM 1 Hour	activities and the schedule for bringing issues to future Steering Group meetings	Theresa Mullin, OPPL Jane Axelrad, CDER Ann Wion, OCC Malcolm Bertoni, OPPL Frank Claunts, OM Deborah Henderson, CDER Ralph Lillie, CDER Nancy Boocker, CDER Karen Meister, OL Patricia Stewart, OPPL Roger McClung, HHS **PhRMA:** Alan Goldhammer, PhRMA Scott Lassman, PhRMA Lynne Tracey, Procter & Gamble Sharon Olmstead, Schering Plough Bill Rosen, Pfizer Annetta Beauregard, Eli Lilly Bruce Burlington, Wyeth Peter Loupos, Sanofi-Aventis Tony Rogers, AstraZeneca **BIO:** Alison Lawton, Genzyme Kay Holcombe, Genzyme Roy Baranello, Wyeth Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO Bob Pietrusko, Millennium Andrew Emmett, BIO
7/27/06 1:00 to 4:00 PM 3 Hours	• The inflation adjustor proposal • The workload adjustor proposal • Current status of CDER/CBER resources • Trademark review process proposal	**FDA:** Theresa Mullin, OPPL Ann Wion, OCC Malcolm Bertoni, OPPL Frank Claunts, OM John Jenkins, CDER Robert Yetter, CBER Deborah Henderson, CDER Jane Axelrad, CDER

Date Time Length	Subjects	Participants
	• Financial baseline and funding levels	Ralph Lillie, CDER Nancy Boocker, CDER Karen Meister, OL Martha Louviere, OM Jonathan Mathieu, OPPL Roger McClung, HHS Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Scott Lassman, PhRMA Lynne Tracey, Procter & Gamble Sharon Olmstead, Schering Plough Bill Rosen, Pfizer Annetta Beauregard, Eli Lilly Bruce Burlington, Wyeth Peter Loupos, Sanofi-Aventis tcon) Tony Rogers, AstraZeneca (tcon) Gretchen Dieck, Pfizer (tcon) Bob Lee, Eli Lilly (tcon) **BIO:** Alison Lawton, Genzyme Kay Holcombe, Genzyme Roy Baranello, Wyeth (tcon) Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO Bob Pietrusko, Millennium (tcon) Andrew Emmett, BIO
8/3/06 Teleconference 1:00 to 2:00 PM 1 Hour	• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings	**FDA:** Theresa Mullin, OPPL Ann Wion, OCC Malcolm Bertoni, OPPL Frank Claunts, OM Robert Yetter, CBER Martha Louviere, OM Deborah Henderson, CDER Jane Axelrad, CDER Ralph Lillie, CDER

Date Time Length	Subjects	Participants
		Nancy Boocker, CDER Karen Meister, OL Roger McClung, HHS Howard Chazin, CDER Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Tricia de Santis, Johnson and Johnson Bill Rosen, Pfizer Annetta Beauregard, Eli Lilly Peter Loupos, Sanofi-Aventis Gretchen Dieck, Pfizer Tony Rogers, AstraZeneca **BIO:** Alison Lawton, Genzyme Kay Holcombe, Genzyme Roy Baranello, Wyeth Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO Andrew Emmett, BIO
8/10/06 Teleconference 1:00 to 2:00 PM 1 Hour	• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings	**FDA:** Theresa Mullin, OPPL Ann Wion, OCC Malcolm Bertoni, OPPL Frank Claunts, OM John Jenkins, CDER Martha Louviere, OM Ralph Lillie, CDER Jane Axelrad, CDER Nancy Boocker, CDER Roger McClung, HHS Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Bruce Burlington, Wyeth Bill Rosen, Pfizer

Date Time Length	Subjects	Participants
		Annetta Beauregard, Eli Lilly Peter Loupos, Sanofi-Aventis Gretchen Dieck, Pfizer Tony Rogers, AstraZeneca Scott Lassman, PhRMA **BIO:** Alison Lawton, Genzyme Sara Radcliffe, BIO Donna Peterson, Amgen Andrew Emmett, BIO
8/24/06 Teleconference 1:00 to 2:00 PM 1 Hour	• Status of subgroup activities and the schedule for bringing issues to future Steering Group meetings • Next steps in FDA compliance with Public Accountability requirement for PDUFA reauthorization	**FDA:** Theresa Mullin, OPPL Ann Wion, OCC Malcolm Bertoni, OPPL Frank Claunts, OM John Jenkins, CDER Robert Yetter, CBER Ralph Lillie, CDER Jane Axelrad, CDER Nancy Boocker, CDER Roger McClung, HHS Karen Meister, OL Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Tricia de Santis, Johnson & Johnson Lynne Tracey, Proctor & Gamble Scott Lassman, PhRMA Peter Loupos, Sanofi-Aventis **BIO:** Bob Pietrusko, Millenium Amit Sachdev, BIO Roy Baranello, Wyeth Sara Radcliffe, BIO Kaye Holcolme, Genzyme Andrew Emmett, BIO
8/31/06 Teleconference	• Status of subgroup activities and the schedule for bringing	**FDA:** Theresa Mullin, OPPL Frank Claunts, OM

Date Time Length	Subjects	Participants
1:00 to 2:00 PM 1 Hour	issues to future Steering Group meetings	Malcolm Bertoni, OPPL Martha Louviere, OM Robert Yetter, CBER Deborah Henderson, CDER Ralph Lillie, CDER Jane Axelrad, CDER Nancy Boocker, CDER Roger McClung, HHS Karen Meister, OL Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Tricia de Santis, Johnson & Johnson Bruce Burlington, Wyeth Sharon Olmstead, Schering Plough Lynne Tracey, Proctor & Gamble Scott Lassman, PhRMA Peter Loupos, Sanofi-Aventis Bill Rosen, Pfizer Annette Beauregard, Eli Lilly **BIO:** Bob Pietrusko, Millenium Amit Sachdev, BIO Roy Baranello, Wyeth Sara Radcliffe, BIO Kaye Holcolme, Genzyme
9/7/06 1:00 to 5:00 PM 4 Hours	• Discussion of proposed inflation adjustor and workload adjustor with a complexity factor • Discussion of method for calculating the proposed PDUFA financial baseline in FY 2008. • Discuss FDA proposal for 9 technical fixes	**FDA:** Theresa Mullin, OPPL Frank Claunts, OM Ann Wion, OCC Malcolm Bertoni, OPPL John Jenkins, CDER Robert Yetter, CBER Deborah Henderson, CDER Martha Louviere, OM Ralph Lillie, CDER Jane Axelrad, CDER Nancy Boocker, CDER Michael Jones, CDER (tcon)

Date Time Length	Subjects	Participants
		Karen Meister, OL Roger McClung, HHS Jonathan Mathieu, OPPL Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Tricia de Santis, Johnson & Johnson Bruce Burlington, Wyeth Sharon Olmstead, Schering Plough Scott Lassman, PhRMA Bill Rosen, Pfizer Peter Loupos, Sanofi-Aventis Tony Rogers, AztraZeneca Annette Beauregard, Eli Lilly Chin Koerner, Novartis Edward Tripp, Abbot Lynne Tracey, Proctor & Gamble (tcon) **BIO:** Bob Pietrusko, Millenium Amit Sachdev, BIO Roy Baranello, Wyeth Sara Radcliffe, BIO Kay Holcombe, Genzyme Andrew Emmett, BIO Alison Lawton, Genzyme Donna Peterson, Amgen

9/8/06
 	
1:00 to 5:00 PM
 	
4 Hours
	• Discussion of proposed inflation adjustor and workload adjustor with a complexity factor
	• Discussion of method for calculating the proposed PDUFA financial baseline in FY 2008.
	  • Discuss safety program proposal
	  • Discuss electronic
		FDA:
		Theresa Mullin, OPPL
		Frank Claunts, OM
		Ann Wion, OCC
		Malcolm Bertoni, OPPL
		John Jenkins, CDER
		Robert Yetter, CBER
		Deborah Henderson, CDER
		Martha Louviere, OM
		Ralph Lillie, CDER
		Jane Axelrad, CDER

Date Time Length	Subjects	Participants
	review environment proposal • Discussion of proposal for timelines for labeling and post marketing commitment (PMC) discussions	Nancy Boocker, CDER Michael Jones, CDER (tcon) Karen Meister, OL Roger McClung, HHS (tcon) Howard Chazin, CDER Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Tricia de Santis, Johnson & Johnson Bruce Burlington, Wyeth Sharon Olmstead, Schering Plough Scott Lassman, PhRMA Gretchen Dieck, Pfizer (tcon) Peter Loupos, Sanofi-Aventis Bill Rosen, Pfizer Annette Beauregard, Eli Lilly Tony Rogers, AztraZeneca Edward Tripp, Abbot Chin Koerner, Novartis Lynne Tracey, Proctor & Gamble (tcon) **BIO:** Bob Pietrusko, Millenium Amit Sachdev, BIO Roy Baranello, Wyeth Sara Radcliffe, BIO Kay Holcombe, Genzyme Andrew Emmett, BIO Donna Peterson, Amgen
9/21/06 1:00 to 3:30 PM 2 ½ Hours	• Continued discussion of proposed enhancements for PDUFA IV • Status of subgroup activities and the schedule for bringing issues to future Steering Group	**FDA:** Theresa Mullin, OPPL Frank Claunts, OM Ann Wion, OCC Malcolm Bertoni, OPPL John Jenkins, CDER Robert Yetter, CBER Deborah Henderson, CDER Martha Louviere, OM

Date Time Length	Subjects	Participants
	meetings	Jane Axelrad, CDER Nancy Boocker, CDER Karen Meister, OL Michael Jones, CDER (tcon) Roger McClung, HHS (tcon) Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Bruce Burlington, Wyeth Gretchen Dieck, Pfizer (tcon) Bill Rosen, Pfizer Scott Lassman, PhRMA (tcon) Tony Rogers, AztraZeneca Peter Loupos, Sanofi-Aventis tcon) Annette Beauregard, Eli Lilly tcon) Tricia de Santis, Johnson & Johnson (tcon) Sharon Olmstead, Schering Plough (tcon) Lynne Tracey, Proctor & Gamble (tcon) **BIO:** Bob Pietrusko, Millenium Amit Sachdev, BIO Roy Baranello, Wyeth Sara Radcliffe, BIO Kay Holcombe, Genzyme Andrew Emmett, BIO Alison Lawton, Genzyme Donna Peterson, Amgen (tcon)
10/5/06 9:00 to 11:00 AM 2 Hours	• Direct to consumer advertising review proposal • Sound financial footing proposals • Proposed resource requirements • Implementation of	**FDA:** Theresa Mullin, OPPL Frank Claunts, OM Ann Wion, OCC Malcolm Bertoni, OPPL John Jenkins, CDER Robert Yetter, CBER Deborah Henderson, CDER

Date Time Length	Subjects	Participants
	• Good review Management Principles (GRMPs) • Proprietary name review	Martha Louviere, OM Ralph Lillie, CDER Jane Axelrad, CDER Michael Jones, CDER (tcon) Roger McClung, HHS Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Bruce Burlington, Wyeth Scott Lassman, PhRMA Gretchen Dieck, Pfizer Bill Rosen, Pfizer Tony Rogers, AztraZeneca (tcon) Annette Beauregard, Eli Lilly Tricia de Santis, Johnson & Johnson (tcon) Sharon Olmstead, Schering Plough Lynne Tracey, Proctor & Gamble (tcon) **BIO:** Bob Pietrusko, Millenium Amit Sachdev, BIO Roy Baranello, Wyeth Sara Radcliffe, BIO Kay Holcombe, Genzyme Andrew Emmett, BIO Alison Lawton, Genzyme Donna Peterson, Amgen (tcon)
10/12/06 Teleconference 1:00 to 1:30 PM ½ Hour	• Workload adjustor complexity factor • Expedited drug development guidances • GRMP implementation proposal • Direct to consumer advertising (DTCA) proposal • Discuss proposal to	**FDA:** Theresa Mullin, OPPL Frank Claunts, OM Ann Wion, OCC Malcolm Bertoni, OPPL John Jenkins, CDER Robert Yetter, CBER Deborah Henderson, CDER Howard Chazin, CDER Ralph Lillie, CDER Jane Axelrad, CDER Michael Jones, CDER

Date Time Length	Subjects	Participants
	eliminate the legislative language that restricts using PDUFA funds to the peri-approval period of 2-3 years post approval	Nancy Boocker, CDER Kaern Meister, OL Patricia Stewart, OPPL **PhRMA:** Alan Goldhammer, PhRMA Tricia de Santis, Johnson & Johnson Petr Loupos, Sanofi-Aventis Sharon Olmstead, Schering Plough Lynne Tracey, Proctor & Gamble Scott Lassman, PhRMA Bill Rosen, Pfizer Gretchen Dieck, Pfizer Annette Beauregard, Eli Lilly Tony Rogers, AztraZeneca **BIO:** Bob Pietrusko, Millenium Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO Kay Holcombe, Genzyme Andrew Emmett, BIO
11/2/06 1:00 to 4:00 PM 3 Hours	• Discuss proposed changes to the commitment letter • Discuss proposed changes to legislative language	**FDA:** Theresa Mullin, OPPL Frank Claunts, OM Ann Wion, OCC Martie Louviere, OM John Jenkins, CDER Mark Gray, OM Deborah Henderson, CDER Jane Axelrad, CDER Ralph Lillie, CDER Michael Jones, CDER Nancy Boocker, CDER Michael Sauers, HHS Ann Sullivan, OPPL Robert Yetter, CBER **PhRMA:** Alan Goldhammer, PhRMA

Date Time Length	Subjects	Participants
		Bruce Burlington, Wyeth Scott Lassman, PhRMA Gretchen Dieck, Pfizer Tony Rogers, AstraZeneca Annetta Beauregard, Eli Lilly Lynne Tracey, Procter & Gamble Tricia de Santis, Johnson and Johnson Peter Loupos, Sanofi-Aventis Bill Rosen, Pfizer **BIO:** Amit Sachdev, BIO Donna Peterson, Amgen Sara Radcliffe, BIO Kay Holcombe, Genzyme Andrew Emmett, BIO Alison Lawton, Genzyme Roy Baranello, Wyeth

Table 2. Finance Subcommittee

Date Time Length	Subject	Participants
4/7/06 1:30 to 3:30PM 2 hours	The following topics were discussed at the meeting: • Future Meetings. • April 21st Meeting Agenda.	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 BIO: Andrew Emmett, BIO Mary McGrane, BIO Donna Peterson, BIO
4/21/06 1:30 to3:30 PM 2 Hours	The following topics were discussed at the meeting: • FDA Appropriated Budget. • Workload Adjuster. • Industry Financial	FDA: Frank Claunts, FDA/OM Roger Eastep, FDA/CBER Kevin Fain, FDA/OCC Mike Jones, FDA/CDER Bob Linkous. FDA/CDER

Date Time Length	Subject	Participants
	Proposals. • FDA Financial Proposals.	Martie Louviere, FDA/OC Jerry Paull, FDA/CBER BIO: Mary McGrane, BIO/Genzyme (Phone) Donna Peterson, BIO/Amgen (Phone) Sara Radcliffe, BIO PhRMA: Alan Goldhammer, PhRMA Don Sauer, PhRMA/Wyeth Lynne Tracey, PhRMA/P&G
5/5/06 1:30 to 3:30 PM 2 Hours	The following topics were discussed at the meeting: • FDA Technical Proposals • Budget Amendment • Inflation Adjuster Proposal • White Oak Costs. • FDA Human Drug Review Process Overhead	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 BIO: Mary McGrane, BIO/Genzyme (by phone) Donna Peterson, BIO/Amgen Sara Radcliffe, BIO PhRMA: Alan Goldhammer, PhRMA Dave Keaney, PhRMA/Novartis Don Sauer, PhRMA/Wyeth Lynne Tracey, PhRMA/P&G (by phone)
5/19/06 1:30 to 3:30 PM	The following topics were discussed at the meeting: • Technical Proposals. • Inflation Adjustment	FDA: Russ Abbott, FDA/CDER Jane Axelrad, FDA/CDER Nancy Boocker, FDA/CDER

Date Time Length	Subject	Participants
2 hours	Proposal. • FDA PDUFA III Cost Review. • PDUFA III Base Resources. • Unit Cost Data. • Financial Baseline • FTE Module.	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 BIO: Andrew Emmett, BIO Donna Peterson, BIO/Amgen Sara Radcliffe, BIO PhRMA: Alan Goldhammer, PhRMA Don Sauer, PhRMA/Wyeth Lynne Tracey, PhRMA/P&G
6/2/06 1:30 to 3:30 PM 2 hours	The following topics were discussed at the meeting: • Technical Proposals. • Inflation Adjustment Proposal. • Review FDA Process for Estimating FTE/Dollars. • Inflation adjustment of user fee trigger for spending from appropriations	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 BIO: Andrew Emmett, BIO Donna Peterson, BIO/Amgen Sara Radcliffe, BIO Mary McGrane, BIO/Genzyme (by phone) PhRMA: Alan Goldhammer, PhRMA Don Sauer, PhRMA/Wyeth Lynne Tracey, PhRMA/P&G
6/16/06	The following topics were	FDA:

Date Time Length	Subject	Participants
	discussed at the meeting: • FDA Contracts • Workload Adjuster Presentation. • Technical Amendments • Remaining Technical Amendments. Inflation Adjustment Proposal. Financial Baseline Proposal. • Future Tasks.	Frank Claunts, FDA/OM Roger Eastep, FDA/CBER Kevin Fain, FDA/OCC Mike Jones, FDA/CDER Bob Linkous. FDA/CDER Martie Louviere, FDA/OC 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: • 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)

Date Time Length	Subject	Participants
7/14/06 1:30 to 3:30 PM 2 hours	The following topics were discussed at the meeting: • 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: • FDA Revenue Estimates. • Inflation Adjustment. • Workload Adjuster.	FDA: Frank Claunts, FDA/OM Roger Eastep, FDA/CBER Kevin Fain, FDA/OCC Mike Jones, FDA/CDER (by phone) Jonathan Matheau, FDA/OP Jerry Paull, FDA/CBER BIO: Andrew Emmett, BIO Mary McGrane, BIO/Genzyme (by phone) Donna Peterson, BIO/Amgen Sara Radcliffe, BIO (by phone) PhRMA: Alan Goldhammer, PhRMA Jeff Jeffress, The Boston Consulting Group Lynne Tracey, PhRMA/P&G (by phone)
7/28/06 1:30 to	The following topics were discussed at the meeting: • Pending Issues.	FDA: Frank Claunts, FDA/OM Nancy Boocker, FDA/CDER

Date Time Length	Subject	Participants
3:30 PM 2 hours	• Workload Adjuster.	Roger Eastep, FDA/CBER Mike Jones, FDA/CDER Martie Louviere, FDA/OC Jonathan Matheau, FDA/OP Jerry Paull, FDA/CBER BIO: Andrew Emmett, BIO Donna Peterson, BIO/Amgen Sara Radcliffe, BIO (by phone) 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)
8/25/06 1:30 to 3:30 PM 2 hours	The following topics were discussed at the meeting: • Draft Proposed Statutory and Legislative History Language. • Workload Adjuster. • Indirect Costs/Overhead.	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 BIO: Andrew Emmett, BIO Mary McGrane, BIO/Genzyme (by phone) Donna Peterson, BIO/Amgen Sara Radcliffe, BIO (by phone) PhRMA: Alan Goldhammer, PhRMA

Table 3. Pre-Market Review Subgroup

Date Time Length	Subject	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 04/07/06 cont'd	• 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	• Proposal regarding labeling discussions • Discuss meeting management proposals • FDA response to data	FDA John Jenkins, CDER Robert Yetter, CBER Kim Colangelo, CDER Chris Joneckis, CBER

Date Time Length	Subject	Participants
2 Hours	requests for commercial INDs submitted, clinical holds of commercial INDs, and clinical special protocol assessments submitted • Discuss Postmarketing Study Commitment proposals	Michael Lanthier, CDER Robert Meyer, CDER Lynn Whipkey Mehler, FDA (via telephone) PhRMA 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 05/05/06 cont'd	• 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-	• Discussion of critical path • Discussion of	FDA John Jenkins, CDER Robert Yetter, CBER

Date Time Length	Subject	Participants
12:00 pm 2 Hours	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	Kim Colangelo, CDER Chris Joneckis, CBER Michael Lanthier, CDER Robert Meyer, CDER Rachel Behrman, FDA Howard Chazin, CDER/FDA <u>PhRMA</u> Bruce Burlington, Wyeth (via telephone) Alan Goldhammer, PhRMA Sharon Olmstead, Schering Plough Greg Brophy, Lilly <u>BIO</u> 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 3 Hours	• FDA presentation of special study on time/level of effort 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	<u>FDA</u> John Jenkins, CDER 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 <u>PhRMA</u> Bruce Burlington, Wyeth Alan Goldhammer, PhRMA Sharon Olmstead, Schering Plough Greg Brophy, Lilly <u>BIO</u> Roy Baranello, Wyeth

Date Time Length	Subject	Participants
		Andrew Emmett, BIO Doug Dobak, AstraZeneca Kay Holcombe, Genzyme Sara Radcliffe, BIO
06/16/06 10:00- 12:00 pm 2 Hours 06/16/06 cont'd	• Discussion of critical path to drug development • Discussion of proposal to discontinue CMA Pilots • Continued discussion of proposals intended to improve application quality	<u>FDA</u> 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 <u>PhRMA</u> Bruce Burlington, Wyeth Alan Goldhammer, PhRMA Greg Brophy, Lilly Sharon Olmstead, Schering Plough <u>BIO</u> 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	<u>FDA</u> 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 <u>PhRMA</u> Bruce Burlington, Wyeth Alan Goldhammer, PhRMA

Date Time Length	Subject	Participants
		Jeff Jeffress, Boston Consulting Group Greg Brophy, Lilly <u>BIO</u> 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 7/14/06 cont'd	• Discussion of FDA meeting and SPA workload • Discussion of the modified workload adjuster proposal	<u>FDA</u> 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 <u>PhRMA</u> Bruce Burlington, Wyeth Alan Goldhammer, PhRMA Greg Brophy, Lilly Martha Brumfield, Pfizer Sharon Olmstead, Schering Plough Jeff Jeffress, Boston Consulting Group (via telephone) <u>BIO</u> Andrew Emmett, BIO Roy Baranello, Wyeth Doug Dobak, AstraZeneca Kay Holcombe, Genzyme Sara Radcliffe, BIO
7/28/06 9:00-12:00	• Discussion of proposed projects to expedite drug development	John Jenkins, CDER Robert Yetter, CBER Kim Colangelo, CDER

Date Time Length	Subject	Participants
pm 3 Hours		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) <u>PhRMA</u> Bruce Burlington, Wyeth Alan Goldhammer, PhRMA Greg Brophy, Lilly Sharon Olmstead, Schering Plough Jeff Jeffress, Boston Consulting Group <u>BIO</u> 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	<u>FDA</u> 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 <u>PhRMA</u> Bruce Burlington, Wyeth Alan Goldhammer, PhRMA Greg Brophy, Lilly Martha Brumfield, Pfizer Derrick Fu, PhRMA (via telephone) <u>BIO</u>

Date Time Length	Subject	Participants
		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	<u>FDA</u> John Jenkins, CDER Robert Yetter, CBER Kim Colangelo, CDER Mike Lanthier, CDER <u>PhRMA</u> Alan Goldhammer, PhRMA Martha Brumfield, Pfizer Sharon Olmstead, Schering Plough <u>BIO</u> 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	<u>FDA</u> 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) <u>PhRMA</u> Alan Goldhammer, PhRMA Greg Brophy, Lilly Martha Brumfield, Pfizer Sharon Olmstead, Schering Plough (via

Date Time Length	Subject	Participants
		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 timelines	FDA John Jenkins, CDER Robert Yetter, CBER Kim Colangelo, CDER Mike Lanthier, CDER 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

Date Time Length	Subject	Participants
		Roy Baranello, Wyeth Doug Dobak, AstraZeneca (via telephone) Kay Holcombe, Genzyme

Table 4. Postmarketing Safety Subgroup

DATE TIME LENGTH	SUBJECT	PARTICIPANTS
March 29, 2006 10:00 a.m. – Noon 2 hours	Agree to issues that the subgroup will consider and some initial timelines for deliverables	**FDA:** Debbie.Henderson, CDER Miles Braun, CBER Ralph Lillie, CDER Heidi Gertner, OCC Julie Beitz, CDER Anne Henig, CDER **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 **BIO:** Andrew Emmett, BIO Kay Holcombe, Genzyme Sara Radcliffe, BIO Bob Pietrusko, Millennium Phil Noguchi, Amgen
April 6, 2006 10:00 a.m. – Noon 2 hours	Presentation of FDA's proposal on how to enhance PDUFA-funded surveillance capacity.	**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 **PhRMA:** Alan Goldhammer, PhRMA Jim Kotsanos, Eli Lilly

		Scott Lassman, PhRMA Gretchen Dieck, Pfizer Dave Pizzuti, Johnson & Johnson **BIO:** Andrew Emmett, BIO Joanna Haas, Genzyme Sara Radcliffe, BIO Kay Holcombe, Genzyme Bob Pietrusko, Millennium Phil Noguchi, Amgen
April 20, 2006 10:00 a.m. – Noon 2 hours	Presentation of FDA's proposals: Epidemiology Methods and Best Practices and Risk Minimization Plans	**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 **PhRMA:** Alan Goldhammer, PhRMA Jim Kotsanos, Eli Lilly Scott Lassman, PhRMA Gretchen Dieck, Pfizer **BIO:** Andrew Emmett, BIO Kay Holcombe, Genzyme Sara Radcliffe, BIO Bob Pietrusko, Millennium
May 4, 2006 10:00 a.m. – 1:00 p.m. 3 hours	Trademark Proposals	**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 **PhRMA:** Steve Hartman, Novartis Bob Lee, Lilly Doug Doban, Astra-Zeneca Scott Lassman, PhRMA Kathy Gans-Brangs, Astra-Zeneca

		BIO: Andrew Emmett, BIO Kay Holcombe, Genzyme Sara Radcliffe, BIO Bob Pietrusko, Millennium
May 18, 2006 10:00 a.m. – Noon 2 hours	Resources needed for post marketing surveillance	**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 **PhRMA** Alan Goldhammer, PhRMA Gretchen Dieck, Pfizer Dave Pizzuti, Johnson & Johnson **BIO:** Andrew Emmett, BIO Sara Radcliffe, BIO
June 1, 2006 10:00 a.m. – Noon 2 hours	Follow up to resource discussion. OSE presentation on vision for postmarket surveillance and epidemiology	**FDA**: Debbie.Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER Gerald DalPan, CDER Bob Ball, CBER Judy Staffa, CDER **PhRMA:** Alan Goldhammer, PhRMA Jim Kotsanos, Lilly Scott Lassman, PhRMA Linda Carter, Johnson and Johnson Gretchen Dieck, Pfizer **BIO:** Andrew Emmett, BIO Bob Pietrusko, Millenium Sara Radcliffe, BIO Kay Holcombe, Genzyme
June 19, 2006 T-con between FDA and Industry 1:30 – 2:30 p.m.	Steps needed to move forward	**FDA**: Debbie.Henderson, CDER Ralph Lillie, CDER **PhRMA:** Alan Goldhammer, PhRMA Jim Kotsanos, Lilly Scott Lassman, PhRMA

1 hour		Gretchen Dieck, Pfizer **BIO:** Bob Pietrusko, Millenium
June 29, 2006 10:00 a.m. – 1:00 p.m. 3 hours	Tradename Discussion	**FDA:** Debbie.Henderson, CDER Carol Holquist, CDER Ralph Lillie, CDER Anne Henig, CDER **PhRMA:** Bob Lee, Lilly Kathy Gans-Brangs, Astra-Zeneca Steve Hartman, Novartis Scott Lassman, PhRMA **BIO:** Kay Holcombe, Genzyme Bob Pietrusko, Millenium
July 5, 2006 T-con between FDA and Industry 8:00 – 9:00 a.m. 1 hour	Finalize Tradename Proposal	**FDA:** Debbie.Henderson, CDER Judy Staffa, CDER Ralph Lillie, CDER Heidi Gertner, OCC Carol Holquist, CDER Anne Henig, CDER Bob Sausville, CBER **PhRMA:** Alan Goldhammer, PhRMA Kathy Gans-Brangs, Astra-Zeneca Scott Lassman, PhRMA Steve Hartman, Novartis Gretchen Dieck, Pfizer Bob Lee, Lilly Jim Kotsanos, Lilly **BIO:** Bob Pietrusko, Millenium Kay Holcombe, Genzyme Andrew Emmett, BIO Sara Radcliffe, BIO
July 6, 2006 9:00 – 11:00 a.m. 2 hours	Tradename Proposal	**FDA:** Debbie.Henderson, CDER Judy Staffa, CDER Ralph Lillie, CDER Heidi Gertner, OCC Anne Henig, CDER **PhRMA:** Alan Goldhammer, PhRMA Gretchen Dieck, Pfizer

		Scott Lassman, PhRMA Jim Kotsanos, Lilly **BIO:** Bob Pietrusko, Millenium Kay Holcombe, Genzyme Andrew Emmett, BIO Sara Radcliffe, BIO
July 11, 2006 T-con between FDA and Industry 8:00 – 9:00 a.m.	Further discussion on Trademark Proposal	**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 **PhRMA:** Alan Goldhammer, PhRMA Bob Lee, Lilly Steve Hartman, Novartis Kathy Gans-Brangs, Astra-Zeneca **BIO:** Bob Pietrusko, Millenium Kay Holcombe, Genzyme Sra Radcliffe, BIO
July 24, 2006 T-con between FDA and Industry 11:00 a.m. – Noon 1 hour	Status of PDUFA document development	**FDA**: Debbie.Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER **PhRMA:** Alan Goldhammer, PhRMA Jim Kotsanos, Lilly Gretchen Dieck, Pfizer **BIO:** Bob Pietrusko, Millenium
July 25, 2006 T-con between FDA and Industry 8:00 – 9:00 a.m. 1 hour	PDUFA Trademark Discussion	**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 **PhRMA:**

		Alan Goldhammer, PhRMA Scott Lassman, PhRMA Bob Lee, Lilly Kathy Gans-Brangs, Astra-Zeneca **BIO:** Kay Holcombe, Genzyme Bob Pietrusko, Millenium
July 27, 2006 9:30 – 11:30 a.m. 2 hours	Trademark Review Proposal	**FDA**: Debbie.Henderson, CDER Ralph Lillie, CDER Anne Henig, CDER Mary Willy, CDER Heidi Gertner, OCC **PhRMA:** Alan Goldhammer, PhRMA Gretchen Dieck, Pfizer Jim Kotsanos, Lilly **BIO:** Kay Holcombe, Genzyme Andrew Emmett, BIO Sara Radcliffe, BIO
August 3, 2006 10:00 a.m. – Noon 2 hours	Review of draft proposal	**FDA:** Debbie Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER Heidi Gertner, OCC **PhRMA:** Jim Kotsanos, Lilly Scott Lassman, PhRMA, Alan Goldhammer, PhRMA Gretchen Dieck, Pfizer **BIO**: Andrew Emmett, BIO Kay Holcombe, Genzyme Sara Radcliffe, BIO
August 24, 2006 10:00 a.m. – Noon 2 hours	Discussion of the Enhancement and Modernization of the FDA Drug Safety System document	**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 **PhRMA:**

		Alan Goldhammer, PhRMA Jim Kotsanos, Lilly Scott Lassman, PhRMA, Gretchen Dieck, Pfizer **BIO**: Andrew Emmett, BIO Sara Radcliffe, BIO Kay Holcombe, Genzyme Bob Pietrusko, Millenium
August 31, 2006 10:00 a.m. – Noon 2 hours	Discussion of the Enhancement and Modernization of the FDA Drug Safety System document	**FDA:** Debbie Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER Judy Staffa, CDER Julie Beitz, CDER Miles Braun CBER **PhRMA:** Alan Goldhammer, PhRMA Jim Kotsanos, Lilly Scott Lassman, PhRMA **BIO**: Bob Pietrusko, Millenium Sara Radcliffe, BIO Kay Holcombe, Genzyme
September 7, 2006 T-con between FDA and Industry 9:00 – 10:00 a.m. 1 hour	Discussion of the Enhancement and Modernization of the FDA Drug Safety System document	**FDA:** Debbie Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER Judy Staffa, CDER Julie Beitz, CDER Miles Braun, CBER **PhRMA:** Alan Goldhammer, PhRMA Gretchen Dieck, Pfizer Scott Lassman, PhRMA **BIO**: Bob Pietrusko, Millenium Andrew Emmett, BIO Sara Radcliffe, BIO Kay Holcombe, Genzyme
October 12, 2006 T-con between FDA and Industry 9:00 – 11:00	Discuss current goals letter and interface with IOM report	**FDA:** Debbie Henderson, CDER Anne Henig, CDER Ralph Lillie, CDER Judy Staffa, CDER Julie Beitz, CDER

p.m. 2 hours		Heidi Gertner, OCC **PhRMA:** Alan Goldhammer, PhRMA Gretchen Dieck, Pfizer Scott Lassman, PhRMA Jim Kotsanos, Lilly **BIO**: Bob Pietrusko, Millenium Andrew Emmett, BIO Sara Radcliffe, BIO

TABLE 5. IT/IM Subgroup

Meeting Date	Meeting Time	Meeting Length	Subject	Participants
03/29/06	2:00 p.m.	2 hours	• Kickoff Meeting • Preliminary list of IT sub-group issues for discussion	Malcolm Bertoni, FDA Fred Farmer, FDA Mark Gray, FDA Len Wilson, FDA Margo Burnette, FDA Peter Beckerman, FDA Rachel Carle, Genzyme Joe Quinn, sanofi pasteur (BIO) Andrew Emmett, BIO Bob Birmingham, Johnson & Johnson PRD Edward Tripp, Abbott Laboratories Peter Loupos, sanofi aventis Bill Rosen, Pfizer Alison Lawton, Genzyme Steve Ward, Lilly
04/19/06	1:00 p.m.	2 hours	• Questions and Clarifications ➢ PhRMA/BIO IT Data Request ➢ Cross-cutting Issues (Safety & DDMAC) ➢ PDUFA III - Follow-	Malcolm Bertoni, FDA Fred Farmer, FDA Mark Gray, FDA Len Wilson, FDA Margo Burnette, FDA Armando Oliva, FDA

Meeting Date	Meeting Time	Meeting Length	Subject	Participants
			up on three areas identified in industry presentation (3/29) o eCTD o Electronic signatures o Secure email • Communication and technical interactions ➢ Industry perspective ➢ Informative presentation - FDA Governance Process	Allen Jones, GSK Joe Quinn, sanofi pasteur (BIO) Andrew Emmett, BIO Bob Birmingham, Johnson & Johnson PRD Bill Rosen, Pfizer Rachel Carle, Genzyme Peter Loupos, sanofi aventis Steve Ward, Lilly Edward Tripp, Abbott Laboratories
05/03/06	1:00 p.m.	2 hours	• Status of date on PDUFA IT spending during since PDUFA I • IT Standards and interoperability	Malcolm Bertoni, FDA Fred Farmer, FDA Mark Gray, FDA Len Wilson, FDA Margo Burnette, FDA Peter Beckerman, FDA Peter Loupos, sanofi aventis Bill Rosen, Pfizer Andrew Emmett, BIO Joe Quinn, sanofi pasteur (BIO) Edward Tripp, Abbott Laboratories Alison Lawton, Genzyme Monica Mehta, Genzyme Steve Ward, Lilly Bob Birmingham, Johnson & Johnson PRD
05/05/06	1:30 p.m.	90 minutes	Discuss concept of shared information exchange	Malcolm Bertoni, FDA Fred Farmer, FDA Gary Gensinger, FDA Mark Gray, FDA

Meeting Date	Meeting Time	Meeting Length	Subject	Participants
				Margo Burnette, FDA Peter Beckerman, FDA Ginger Leo, FDA Peter Loupos, sanofi aventis Bill Rosen, Pfizer Andrew Emmett, BIO Bob Birmingham, Johnson & Johnson PRD Edward Tripp, Abbott Laboratories Allen Jones, GSK Steve Ward, Lilly
05/17/06	1:00 p.m.	2 hours	FDA PDUFA IV cost estimate	Malcolm Bertoni, FDA Armando Oliva, FDA Mark Gray, FDA Len Wilson, FDA Margo Burnette, FDA Peter Loupos, sanofi aventis Bill Rosen, Pfizer Andrew Emmett, BIO Joe Quinn, sanofi pasteur (BIO) Edward Tripp, Abbott Laboratories Alan Goldhammer, PhRMA Steve Ward, Lilly Alison Lawton, Genzyme Rachel Carle, Genzyme Bob Birmingham, Johnson & Johnson PRD
05/24/06	8:30 a.m.	1 hour	Follow-up on FDA IT cost estimate	Malcolm Bertoni, FDA Mark Gray, FDA Margo Burnette, FDA Ginger Leo, FDA

Meeting Date	Meeting Time	Meeting Length	Subject	Participants
				Tim Mahoney, FDA Andrew Emmett, BIO Joe Quinn, sanofi pasteur (BIO) Bob Birmingham, Johnson & Johnson PRD Steve Ward, Lilly Bill Rosen, Pfizer
05/31/06	1:00 p.m.	2 hours	• Discuss possible language for IT/IM 'Communication and technical interactions' area. • Discuss PDUFA III IT performance goals • Follow-up on FDA IT cost estimate	Malcolm Bertoni, FDA Fred Farmer, FDA Mark Gray, FDA Len Wilson, FDA Armando Oliva, FDA Andrew Emmett, BIO Edward Tripp, Abbott Laboratories Len Wilson, FDA Joe Quinn, sanofi pasteur (BIO) Bob Birmingham, Johnson & Johnson PRD Rachel Carle, Genzyme Peter Loupos, sanofi Aventis Steve Ward, Lilly Bill Rosen, Pfizer

06/14/06	1:00 p.m.	2 hours	• Communication and technical interactions
			  • Definition of 'end-to-end electronic submissions'
			  • Discuss commitment letter language
				Malcolm Bertoni, FDA
				Fred Farmer, FDA
				Mark Gray, FDA
				Len Wilson, FDA
				Armando Oliva, FDA
				Margo Burnette, FDA
				Bill Rosen, Pfizer
				Andrew Emmett, BIO
				Edward Tripp, Abbott Laboratories
				Joe Quinn, sanofi

Meeting Date	Meeting Time	Meeting Length	Subject	Participants
				pasteur (BIO) Bob Birmingham, Johnson & Johnson PRD Rachel Carle, Genzyme Peter Loupos, sanofi Aventis Steve Ward, Lilly Alan Goldhammer, PhRMA Alison Lawton, Genzyme

06/28/06	9:00 a.m.	2 hours	• Commitment letter language on Communication and Technical Interactions
			• PDUFA IV IT Discussion Framework
			  • Performance Goals
			  • IT cost
				Malcolm Bertoni, FDA
				Len Wilson, FDA
				Mark Gray, FDA
				Armando Oliva, FDA
				
				Margo Burnette, FDA
				Edward Tripp, Abbott Laboratories
				Andrew Emmett, BIO
				Steve Ward, Lilly
				
				Bob Birmingham, Johnson & Johnson PRD
				Rachel Carle, Genzyme

06/28/06	1:00 p.m.	2 hours		Malcolm Bertoni, FDA Fred Farmer, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Edward Tripp, Abbott Laboratories Andrew Emmett, BIO Steve Ward, Lilly

Meeting Date	Meeting Time	Meeting Length	Subject	Participants
				Bob Birmingham, Johnson & Johnson PRD Rachel Carle, Genzyme Bill Rosen, Pfizer Alan Goldhammer, PhRMA
07/12/06	9:00 a.m.	2 hours	• Discuss commitment letter language on Communication and Technical Interactions • Industry perspective o Their priorities o Standards and technical plans • Metrics and Measures	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Peter Loupos, sanofi aventis Andrew Emmett, BIO Bill Rosen, Pfizer Rachel Carle, Genzyme Allen Jones, GSK Joe Quinn, sanofi pasteur (BIO) Edward Tripp, Abbott Laboratories Bob Birmingham, Johnson & Johnson PRD
07/12/06	1:00 p.m.	2 hours		Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Peter Loupos, sanofi aventis Andrew Emmett, BIO Bill Rosen, Pfizer Rachel Carle, Genzyme Allen Jones, GSK Joe Quinn, sanofi

Meeting Date	Meeting Time	Meeting Length	Subject	Participants
				pasteur (BIO) Edward Tripp, Abbott Laboratories Bob Birmingham, Johnson & Johnson PRD
07/19/06	1:30 p.m.	2 hours	• Discuss commitment letter language o Communications and Technical Interactions o Metrics and Measures o Standards and Technical plans	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Peter Loupos, sanofi aventis Andrew Emmett, BIO Bill Rosen, Pfizer Rachel Carle, Genzyme Allen Jones, GSK Bob Birmingham, Johnson & Johnson PRD
07/26/06	9:00 a.m.	2 hours	• Goals o End-to-end review environment o Industry recommended commitment letter wording • Metrics and Measures • Discuss commitment letter wording o Communications and Technical Interactions o Standards and Technical plans	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Bill Rosen, Pfizer Andrew Emmett, BIO Steve Ward, Lilly Rachel Carle, Genzyme Bob Birmingham, Johnson & Johnson PRD Joe Quinn, sanofi pasteur (BIO) Alan Goldhammer, PhRMA
07/26/06	1:00 p.m.	2 hours		Malcolm Bertoni, FDA

Meeting Date	Meeting Time	Meeting Length	Subject	Participants
				Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Bill Rosen, Pfizer Andrew Emmett, BIO Steve Ward, Lilly Rachel Carle, Genzyme Bob Birmingham, Johnson & Johnson PRD Joe Quinn, sanofi pasteur (BIO) Alan Goldhammer, PhRMA Peter Loupos, sanofi Aventis Allen Jones, GSK
08/02/06	9:00 a.m.	2 hours	Review Industry Goals and Objectives in relation to the Commitment Letter	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Margo Burnette, FDA Armando Oliva, FDA Bill Rosen, Pfizer Andrew Emmett, BIO Steve Ward, Lilly Rachel Carle, Genzyme Bob Birmingham, Johnson & Johnson PRD Joe Quinn, sanofi pasteur (BIO) Alan Goldhammer, PhRMA Edward Tripp, Abbott Laboratories
08/09/06	9:00 a.m.	2 hours	• Discuss IT/IM language for the commitment letter • FDA presentation on the Proposed Funding vs. Flat	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA

Meeting Date	Meeting Time	Meeting Length	Subject	Participants
			Funding	Armando Oliva, FDA Margo Burnette, FDA Bill Rosen, Pfizer Andrew Emmett, BIO Joe Quinn, sanofi pasteur (BIO) Edward Tripp, Abbott Laboratories Alan Goldhammer, PhRMA Allen Jones, GSK Steve Ward, Lilly Rachel Carle, Genzyme
08/09/06	1:00 p.m.	2 hours		Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Bill Rosen, Pfizer Andrew Emmett, BIO Joe Quinn, sanofi pasteur (BIO) Edward Tripp, Abbott Laboratories Alan Goldhammer, PhRMA Allen Jones, GSK Steve Ward, Lilly Rachel Carle, Genzyme
08/16/06	9:00 a.m.	2 hours	• Review of the IT/IM commitment letter language	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Bill Rosen, Pfizer Andrew Emmett, BIO Joe Quinn, sanofi pasteur (BIO) Rachel Carle, Genzyme

Meeting Date	Meeting Time	Meeting Length	Subject	Participants
				Steve Ward, Lilly Bob Birmingham, Johnson & Johnson PRD Allen Jones, GSK
08/16/06	1:00 p.m.	2 hours		Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Bill Rosen, Pfizer Andrew Emmett, BIO Joe Quinn, sanofi pasteur (BIO) Rachel Carle, Genzyme Steve Ward, Lilly Bob Birmingham, Johnson & Johnson PRD Allen Jones, GSK Peter Loupos, sanofi aventis
08/30/06	9:00 a.m.	2 hours	Review of the IT/IM commitment letter language	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Peter Beckerman, FDA Bill Rosen, Pfizer Peter Loupos, sanofi aventis Steve Ward, Lilly Rachel Carle, Genzyme Bob Birmingham, Johnson & Johnson PRD Joe Quinn, sanofi pasteur (BIO) Alan Goldhammer,

Meeting Date	Meeting Time	Meeting Length	Subject	Participants
				PhRMA Edward Tripp, Abbott Laboratories Allen Jones, GSK
09/06/06	11:00 a.m.	1 hour	Review presentation to the PDUFA Steering Committee	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Margo Burnette, FDA Bill Rosen, Pfizer Steve Ward, Lilly Rachel Carle, Genzyme Bob Birmingham, Johnson & Johnson PRD Joe Quinn, sanofi pasteur (BIO) Edward Tripp, Abbott Laboratories Andrew Emmett, BIO Allen Jones, GSK
09/07/06	11:30 a.m.	1 hour	Review presentation to the PDUFA Steering Committee	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Margo Burnette, FDA Peter Loupos, sanofi aventis Bill Rosen, Pfizer Rachel Carle, Genzyme Edward Tripp, Abbott Laboratories
09/15/06	10:00 a.m.	1 hour	Review commitment letter language	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Peter Loupos, sanofi aventis Bill Rosen, Pfizer Rachel Carle,

Meeting Date	Meeting Time	Meeting Length	Subject	Participants
				Genzyme Edward Tripp, Abbott Laboratories
12/06/06	3:00 p.m	30 minutes	PDUFA IV proposal update/status	Malcolm Bertoni, FDA Mark Gray, FDA Margo Burnette, FDA Bill Rosen, Pfizer Steve Ward, Lilly Rachel Carle, Genzyme Joe Quinn, sanofi pasteur (BIO) Alan Goldhammer, PhRMA Edward Tripp, Abbott Laboratories Andrew Emmett, BIO Allen Jones, GSK

Table 6. DTC Sub-Group

Date Time Length	Subjects	Participants
3/30/06 1:00 to 3:00 PM 2 Hours	• FDA proposal for additional PDUFA IV funding for FDA to review DTC broadcast advertisements. • FDA response to industry's data request pertaining to DTC advertising review.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Maryann Gallagher, CBER **PhRMA/BIO:** Tony Rogers, AstraZeneca/PhRMA Preeti Pinto, AstraZeneca/PhRMA Alan Goldhammer, PhRMA Scott Lassman, PhRMA Annetta Beauregard, Eli Lilly/PhRMA Sara Radcliffe, BIO

Date Time Length	Subjects	Participants
		Donna Paterson, Amgen/BIO Andrew Emmett, BIO
4/19/06 1:00 to 3:00 PM 2 Hours	• Additional information about FDA's DTC proposal • Possibility of separate fee for DTC • PhRMA presentation of their Guiding Principles on DTC advertisements.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Maryann Gallagher, CBER Seth Ray, OCC Emily Thakur, CDER **Industry:** Tony Rogers, AstraZeneca/PhRMA Preeti Pinto, AstraZeneca/PhRMA Alan Goldhammer, PhRMA Scott Lassman, PhRMA Annetta Beauregard, Eli Lilly/PhRMA Sara Radcliffe, BIO Patrick Brady, Eli Lilly/PhRMA Minnie Baylor-Henry, J&J/PhRMA
4/26/06 Teleconference 1:00 to 3:00 PM 2 Hours	• FDA's current workload for DTC broadcast review and estimating the number of submissions anticipated if user fees and performance metrics are developed.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Maryann Gallagher, CBER Bob Sausville, CBER Seth Ray, OCC Emily Thakur, CDER **Industry:** Tony Rogers, AstraZeneca/PhRMA Preeti Pinto, AstraZeneca/PhRMA Alan Goldhammer, PhRMA

Date Time Length	Subjects	Participants
		Scott Lassman, PhRMA Annetta Beauregard, Eli Lilly/PhRMA Sara Radcliffe, BIO Donna Peterson, Amgen/BIO Minnie Baylor-Henry, J&J/PhRMA Andrew Emmett, BIO
5/19/06 Teleconference 9:00 to 11:00 AM 2 Hours	• Assumptions for estimating the number of DTC broadcast ad pre-submissions if user fees and performance metrics are adopted. • FDA's current review times for broadcast ad pre-submissions.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Maryann Gallagher, CBER Bob Sausville, CBER Seth Ray, OCC Emily Thakur, CDER **Industry:** Tony Rogers, AstraZeneca/PhRMA Preeti Pinto, AstraZeneca/PhRMA Scott Lassman, PhRMA Annetta Beauregard, Eli Lilly/PhRMA Sara Radcliffe, BIO Donna Paterson, Amgen/BIO Minnie Baylor-Henry, J&J/PhRMA Andrew Emmett, BIO
5/24/06 1:00 to 3:00 PM 2 Hours	• Assumptions for estimating the number of DTC broadcast ad pre-submissions if user fees and performance metrics are adopted. • Possibility of a workload adjustor	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Maryann Gallagher, CBER Seth Ray, OCC Emily Thakur, CDER

Date Time Length	Subjects	Participants
	to account for greater than anticipated workload. • Possible fee funding for DTC broadcast ad review	**Industry:** Tony Rogers, AstraZeneca/PhRMA Scott Lassman, PhRMA Annetta Beauregard, Eli LillyPhRMA Sara Radcliffe, BIO Minnie Baylor-Henry, J&J/PhRMA Andrew Emmett, BIO Alan Goldhamrner, PhRMA Donna Peterson, Amgen/BIO
6/7/06 1:00 to 3:00 PM 2 Hours	• DTC broadcast ad review	**FDA** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Maryann Gallagher, CBER Melissa Moncavage, CDER Seth Ray, OCC Bob Sausville, CBER Emily Thakur, CDER **Industry:** Minnie Baylor-Henry, J&J/PhRMA Andrew Emmett, BIO Alan Goldhammer, PhRMA Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Preeti Pinto, AstraZeneca Sara Radcliffe, BIO Tony Rogers, AstraZeneca/PhRMA
6/21/06 1:00 to 3:00 PM 2 Hours	• Discuss DTC TV advertisement review	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Seth Ray, OCC Bob Sausville, CBER

Date Time Length	Subjects	Participants
		Emily Thakur, CDER **Industry:** Minnie Baylor-Henry, J&J/PhRMA Annetta Beuregard, Lilly Andrew Emmett, BIO Alan Goldhammer, PhRMA Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Preeti Pinto, AstraZeneca Sara Radcliffe, BIO Tony Rogers, AstraZeneca/PhRMA
7/5/06 1:00 to 3:00 PM 2 Hours	• Assumptions and calculations to develop cost estimates for DTC broadcast proposal.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Melissa Moncavage, CDER Bob Sausville, CBER Emily Thakur, CDER **Industry:** Annetta Beauregard, Lilly Andrew Emmett, BIO Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Preeti Pinto, AstraZeneca Sara Radcliffe, BIO Tony Rogers, AstraZeneca/PhRMA
7/19/06 1:00 to 3:00 PM 2 Hours	• Discuss DTC broadcast ad review.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Malcolm Bertoni, OC Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Maryann Gallagher, CBER Mark Gray, OC Bob Sausville, CBER Emily Thakur, CDER **Industry:** Minnie Baylor-Henry,

Date Time Length	Subjects	Participants
		J&J/PhRMA Annetta Beauregard, Lilly Alan Goldhammer, PhRMA Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Preeti Pinto, AstraZeneca Sara Radcliffe, BIO Tony Rogers, AstraZeneca/PhRMA Bill Rosen, Pfizer/PhRMA
8/2/06 Teleconference 1:00 to 3:00 PM 2 Hours	• Concepts for separate fee to fund DTC broadcast ad review.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Maryann Gallagher, CBER Ele Ibarra-Pratt, CBER Emily Thakur, CDER **Industry:** Minnie Baylor-Henry, J&J Annetta Beauregard, Lilly Andrew Emmett, Bio Alan Goldhammer, PhRMA Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Preeti Pinto, AstraZeneca Sara Radcliffe, BIO Tony Rogers, AstraZeneca/PhRMA
8/23/06 1:00 to 3:00 PM 2 Hours	• Discuss financial structure stability if a separate fee for funding DTC broadcast reviews.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Maryann Gallagher, CBER Bob Sausville, CBER **Industry:** Patrick Brady, Eli Lilly/PhRMA Minnie Baylor-Henry, J&J/PhRMA Andrew Emmett, BIO

Date Time Length	Subjects	Participants
		Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Preeti Pinto, AstraZeneca Sara Radcliffe, BIO Tony Rogers, AstraZeneca/PhRMA
8/30/06 Teleconference 1:00 to 2:00 PM 1 Hour	• Discuss financial structure stability if a separate fee for funding DTC broadcast reviews.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Ele Ibarra-Pratt, CBER Melissa Moncavage, CDER Bob Sausville, CBER Emily Thakur, CDER **Industry:** Minnie Baylor-Henry, J&J/PhRMA Annetta Beauregard, Lilly Alan Goldhammer, PhRMA Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Preeti Pinto, AstraZeneca/PhRMA Sara Radcliffe, BIO Tony Rogers, AstraZeneca/PhRMA
9/20/06 1:00 to 5:00 PM 4 Hours	• Discuss approaches to separate user fee funding of DTC broadcast reviews.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Kristin Davis, CDER **Industry:** Andrew Emmett, BIO Scott Lassman, PhRMA Tony Rogers, AstraZeneca/PhRMA
9/21/06 8:00 to 10:30 AM	• Discuss approaches to separate user fee funding of DTC broadcast reviews.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Kristin Davis, CDER **Industry:**

Date Time Length	Subjects	Participants
2.5 Hours		Andrew Emmett, BIO Scott Lassman, PhRMA Tony Rogers, AstraZeneca/PhRMA
9/26/06 Teleconference 1:30 to 2:30 PM 1 Hour	• Discuss approaches to separate user fee funding of DTC broadcast reviews.	**FDA:** Kathryn Aikin, CDER Kristin Davis, CDER Melissa Moncavage, CDER **Industry:** Minnie Baylor-Henry, J&J/PhRMA Annetta Beauregard, Lilly Patrick Brady, Eli Lilly/PhRMA Preeti Pinto, AstraZeneca/PhRMA
9/27/06 1:00 to 3:00 PM 2 Hour	• Discuss proposal for separate user fee funding of DTC broadcast reviews.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Seth Ray, OCC Maryann Gallagher, CBER **Industry:** Minnie Baylor-Henry, Johnson & Johnson/PhRMA Annetta Beauregard, Eli Lilly Andrew Emmett, BIO Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Preeti Pinto, AstraZeneca
10/6/06 8:30 to 10:30 AM 2 Hours	• Discuss possible legislative language	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Kristin Davis, CDER Maryann Gallagher, CBER Eli Ibarra-Pratt, CBER Melissa Moncavage, CDER

Date Time Length	Subjects	Participants
		Seth Ray, OCC **Industry:** Patrick Brady, Eli Lilly Andrew Emmett, BIO Scott Lassman, PhRMA Tony Rogers, AstraZeneca Preeti Pinto, AstraZeneca
10/11/06 Teleconference 8:30 to 10:30 AM 2 Hours	• Discuss possible legislative language	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Maryann Gallagher, CBER **Industry:** Tony Rogers, AstraZeneca /PhRMA Annetta Beauregard, Eli Lilly/PhRMA Andrew Emmett, BIO Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Patrick Brady, Eli Lilly/PhRMA
10/17/06 2:00 to 5:00 PM 3 Hours	• Discuss proposed draft legislative language.	**FDA:** Jane Axelrad, CDER Thomas Abrams, CDER Nancy Booker, CDER Frank Claunts, OC Kristin Davis, CDER Kevin Fain, OCC Maryann Gallagher, CBER (by T-con) Mike Jones, CDER Marty Louviere, OC Eli Ibarra-Pratt, CBER (by T-con) Melissa Moncavage, CDER

Date Time Length	Subjects	Participants
		Kevin Fain, OCC Maryann Gallagher, CBER Mike Jones, CDER Marti Louviere, OC Melissa Moncavage, CDER **Industry:** Minnie Baylor Henry, Johnson and Johnson/PhRMA Annetta Beauregard, Eli Lilly Patrick Brady, Eli Lilly Andrew Emmett, BIO Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Preeti Pinto, AstraZeneca Tony Rogers, AstraZeneca /PhRMA
11/8/06 Teleconference 1:00 to 3:00 PM 2 Hours	• Discuss proposed draft legislative language.	**FDA:** Jane Axelrad, CDER Tom Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Kevin Fain, OCC Maryann Gallagher, CBER Mike Jones, CDER Marti Louviere, OC Melissa Moncavage, CDER Ele Pratt, CBER **Industry:** Patrick Brady, Eli Lilly Andrew Emmett, BIO Alan Goldhammer, PhRMA Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Tony Rogers, AstraZeneca /PhRMA