

**Table 6. PDUFA IV Meetings – Technical Discussions
with Regulated Industry Direct-to-Consumer
Advertising Sub-Group**

Date Time Length	Subjects	Participants
3/30/06 1:00 to 3:00 PM 2 Hours	<ul style="list-style-type: none"> 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. 	<p>FDA: Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Maryann Gallagher, CBER</p> <p>PhRMA/BIO: Tony Rogers, AstraZeneca/PhRMA Preeti Pinto, AstraZeneca/PhRMA Alan Goldhammer, PhRMA Scott Lassman, PhRMA Annetta Beauregard, Eli Lilly/PhRMA Sara Radcliffe, BIO Donna Paterson, Amgen/BIO Andrew Emmett, BIO</p>
4/19/06 1:00 to 3:00 PM 2 Hours	<ul style="list-style-type: none"> Additional information about FDA's DTC proposal Possibility of separate fee for DTC PhRMA presentation of their Guiding Principles on DTC advertisements. 	<p>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</p> <p>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</p>
4/26/06 Teleconference 1:00 to 3:00 PM 2 Hours	<ul style="list-style-type: none"> FDA's current workload for DTC broadcast review and estimating the number of submissions anticipated if user fees and performance metrics are developed. 	<p>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</p>

		<p>Industry: Tony Rogers, AstraZeneca/PhRMA Preeti Pinto, AstraZeneca/PhRMA Alan Goldhammer, PhRMA Scott Lassman, PhRMA Annetta Beauregard, Eli Lilly/PhRMA Sara Radcliffe, BIO Donna Peterson, Amgen/BIO Minnie Baylor-Henry, J&J/PhRMA Andrew Emmett, BIO</p>
<p>5/19/06 Teleconference 9:00 to 11:00 AM 2 Hours</p>	<ul style="list-style-type: none"> 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. 	<p>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</p> <p>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</p>
<p>5/24/06 1:00 to 3:00 PM 2 Hours</p>	<ul style="list-style-type: none"> Assumptions for estimating the number of DTC broadcast ad pre-submissions if user fees and performance metrics are adopted. Possibility of a workload adjustor to account for greater than anticipated workload. Possible fee funding for DTC broadcast ad review 	<p>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</p> <p>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 Goldhammer, PhRMA Donna Peterson, Amgen/BIO</p>
<p>6/7/06 1:00 to 3:00 PM 2 Hours</p>	<ul style="list-style-type: none"> DTC broadcast ad review 	<p>FDA Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER</p>

		<p>Maryann Gallagher, CBER Melissa Moncavage, CDER Seth Ray, OCC Bob Sausville, CBER Emily Thakur, CDER</p> <p>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</p>
<p>6/21/06 1:00 to 3:00 PM 2 Hours</p>	<ul style="list-style-type: none"> Discuss DTC TV advertisement review 	<p>FDA: Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Seth Ray, OCC Bob Sausville, CBER Emily Thakur, CDER</p> <p>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</p>
<p>7/5/06 1:00 to 3:00 PM 2 Hours</p>	<ul style="list-style-type: none"> Assumptions and calculations to develop cost estimates for DTC broadcast proposal. 	<p>FDA: Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Melissa Moncavage, CDER Bob Sausville, CBER Emily Thakur, CDER</p> <p>Industry: Annetta Beuregard, Lilly Andrew Emmett, BIO Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Preeti Pinto, AstraZeneca Sara Radcliffe, BIO Tony Rogers, AstraZeneca/PhRMA</p>
<p>7/19/06 1:00 to 3:00 PM 2 Hours</p>	<ul style="list-style-type: none"> Discuss DTC broadcast ad review. 	<p>FDA: Jane Axelrad, CDER Thomas Abrams, CDER Malcolm Bertoni, OC</p>

		<p>Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Maryann Gallagher, CBER Mark Gray, OC Bob Sausville, CBER Emily Thakur, CDER</p> <p>Industry: Minnie Baylor-Henry, 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</p>
<p>8/2/06 Teleconference 1:00 to 3:00 PM 2 Hours</p>	<ul style="list-style-type: none"> • Concepts for separate fee to fund DTC broadcast ad review. 	<p>FDA: Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Maryann Gallagher, CBER Ele Ibarra-Pratt, CBER Emily Thakur, CDER</p> <p>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</p>
<p>8/23/06 1:00 to 3:00 PM 2 Hours</p>	<ul style="list-style-type: none"> • Discuss financial structure stability if a separate fee for funding DTC broadcast reviews. 	<p>FDA: Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Maryann Gallagher, CBER Bob Sausville, CBER</p> <p>Industry: Patrick Brady, Eli Lilly/PhRMA Minnie Baylor-Henry, J&J/PhRMA Andrew Emmett, BIO Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Preeti Pinto, AstraZeneca Sara Radcliffe, BIO Tony Rogers, AstraZeneca/PhRMA</p>
<p>8/30/06</p>	<ul style="list-style-type: none"> • Discuss financial structure 	<p>FDA:</p>

<p>Teleconference 1:00 to 2:00 PM 1 Hour</p>	<p>stability if a separate fee for funding DTC broadcast reviews.</p>	<p>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</p> <p>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</p>
<p>9/20/06 1:00 to 5:00 PM 4 Hours</p>	<ul style="list-style-type: none"> Discuss approaches to separate user fee funding of DTC broadcast reviews. 	<p>FDA: Jane Axelrad, CDER Thomas Abrams, CDER Kristin Davis, CDER</p> <p>Industry: Andrew Emmett, BIO Scott Lassman, PhRMA Tony Rogers, AstraZeneca/PhRMA</p>
<p>9/21/06 8:00 to 10:30 AM 2.5 Hours</p>	<ul style="list-style-type: none"> Discuss approaches to separate user fee funding of DTC broadcast reviews. 	<p>FDA: Jane Axelrad, CDER Thomas Abrams, CDER Kristin Davis, CDER</p> <p>Industry: Andrew Emmett, BIO Scott Lassman, PhRMA Tony Rogers, AstraZeneca/PhRMA</p>
<p>9/26/06 Teleconference 1:30 to 2:30 PM 1 Hour</p>	<ul style="list-style-type: none"> Discuss approaches to separate user fee funding of DTC broadcast reviews. 	<p>FDA: Kathryn Aikin, CDER Kristin Davis, CDER Melissa Moncavage, CDER</p> <p>Industry: Minnie Baylor-Henry, J&J/PhRMA Annetta Beauregard, Lilly Patrick Brady, Eli Lilly/PhRMA Preeti Pinto, AstraZeneca/PhRMA</p>
<p>9/27/06 1:00 to 3:00 PM 2 Hour</p>	<ul style="list-style-type: none"> Discuss proposal for separate user fee funding of DTC broadcast reviews. 	<p>FDA: Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Seth Ray, OCC Maryann Gallagher, CBER</p>

		<p>Industry: Minnie Baylor-Henry, Johnson & Johnson/PhRMA Annetta Beauregard, Eli Lilly Andrew Emmett, BIO Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Preeti Pinto, AstraZeneca</p>
<p>10/6/06 8:30 to 10:30 AM 2 Hours</p>	<ul style="list-style-type: none"> Discuss possible legislative language 	<p>FDA: Jane Axelrad, CDER Thomas Abrams, CDER Kristin Davis, CDER Maryann Gallagher, CBER Eli Ibarra-Pratt, CBER Melissa Moncavage, CDER Seth Ray, OCC</p> <p>Industry: Patrick Brady, Eli Lilly Andrew Emmett, BIO Scott Lassman, PhRMA Tony Rogers, AstraZeneca Preeti Pinto, AstraZeneca</p>
<p>10/11/06 Teleconference 8:30 to 10:30 AM 2 Hours</p>	<ul style="list-style-type: none"> Discuss possible legislative language 	<p>FDA: Jane Axelrad, CDER Thomas Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Melissa Moncavage, CDER Maryann Gallagher, CBER</p> <p>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</p>
<p>10/17/06 2:00 to 5:00 PM 3 Hours</p>	<ul style="list-style-type: none"> Discuss proposed draft legislative language. 	<p>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</p> <p>Industry: Annetta Beauregard, Eli Lilly (by T-con) Patrick Brady, Eli Lilly (by T-con)</p>

		<p>Andrew Emmett, BIO Alan Goldhammer, PhRMA (by T-con) Scott Lassman, PhRMA Preeti Pinto, AstraZeneca</p>
<p>10/25/06 9:30 to 11:30 AM 2 Hours</p>	<ul style="list-style-type: none"> Discuss proposed draft legislative language. 	<p>FDA: Jane Axelrad, CDER Thomas Abrams, CDER Nancy Booker, CDER Kristin Davis, CDER Kevin Fain, OCC Maryann Gallagher, CBER (by T-con) Mike Jones, CDER Melissa Moncavage, CDER Robert Sausville, CBER (by T-con)</p> <p>Industry: Minnie Baylor-Henry, Johnson and Johnson (by T-con) Annetta Beauregard, Eli Lilly (by T-con) Andrew Emmett, BIO Scott Lassman, PhRMA Preeti Pinto, AstraZeneca Sara Radcliffe, BIO (by T-con) Tony Rogers, AstraZeneca</p>
<p>11/1/06 2:00 to 4:00 PM 2 Hours</p>	<ul style="list-style-type: none"> Discuss proposed draft legislative language. 	<p>FDA: Jane Axelrad, CDER Tom Abrams, CDER Nancy Boocker, CDER Frank Claunts, OC Kristin Davis, CDER Kevin Fain, OCC Maryann Gallagher, CBER Mike Jones, CDER Marti Louviere, OC Melissa Moncavage, CDER</p> <p>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</p>
<p>11/8/06 Teleconference 1:00 to 3:00 PM 2 Hours</p>	<ul style="list-style-type: none"> Discuss proposed draft legislative language. 	<p>FDA: Jane Axelrad, CDER Tom Abrams, CDER Nancy Boocker, CDER Kristin Davis, CDER Kevin Fain, OCC Maryann Gallagher, CBER</p>

		<p>Mike Jones, CDER Marti Louviere, OC Melissa Moncavage, CDER Ele Pratt, CBER</p> <p>Industry: Patrick Brady, Eli Lilly Andrew Emmett, BIO Alan Goldhammer, PhRMA Scott Lassman, PhRMA Donna Peterson, Amgen/BIO Tony Rogers, AstraZeneca /PhRMA</p>
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