

# FOOD AND DRUG ADMINISTRATION

## PART 15 PUBLIC HEARING SCHEDULE

### “Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management”

**December 18, 2006**

<b>Opening Remarks</b>	Janet Woodcock, M.D.  <i>Deputy Commissioner for Operations, FDA</i>	**9:00 a.m.- 9:05 a.m.
<b>Presentations</b>	S. Albert Edwards, Pharm.D. <i>Director, Regulatory Affairs TAP Pharmaceutical Products, Inc.</i>	9:05 a.m. – 9:35 a.m.  (30 min.)
	Thomas W. Littlejohn, M.D. <i>Medical Director Piedmont Medical Group</i>  Doug Pierce <i>President Piermed, Inc.</i>	9:35 a.m. – 10:05 a.m.  (30 min.)
	Ron Celeste <i>ThinSpring</i>	10:05 a.m. – 10:25 a.m. (20 min.)
<b>Break</b>		10:25 a.m. – 10:35 a.m.
	David Hardison, Ph.D. <i>Vice President Life Sciences, SAIC</i>  Wayne Kubick, M.B.A. <i>Sr. Vice President Lincoln Technologies</i>	10:35 a.m. – 11:05 a.m.  (30 min.)
	Kristine Jacobson <i>Surety</i>	11:05 a.m. – 11:20 a.m.  (15 min.)
	Nancy Smerkanich <i>Vice President, Regulatory Affairs Octagon Research Solutions</i>	11:20 a.m. – 11:35 a.m.  (15 min.)
	Marc J. Scheineson or Donald E. Segal <i>Alston &amp; Bird, LLP</i>	11:35 a.m. – 11:55 p.m.  (20 min.)

<b>Lunch</b>		11:55 p.m. – 12:55 p.m.
	<p>Debra Bremer <i>VP Development &amp; Medical Informatics, Pfizer</i></p> <p>Diana McKenzie <i>Executive Director, Information Systems, Amgen</i></p> <p>Sue Dubman <i>VP IT &amp; Informatics Theravance, Inc.</i></p> <p>J. Robert Beck, M.D. <i>VP/CIO Fox Chase Cancer Center</i></p> <p>Diane Paul <i>Patient Advocate</i></p> <p>Bob Renner <i>CEO, Liaison Technologies</i></p> <p>Mark Adams <i>Sr. Associate Booz Allen Hamilton</i></p>	<p>12:55 p.m. – 1:40 p.m.</p> <p>(45 min.)</p>
	<p>Ed Tripp <i>Program Director, eSubmissions Abbott Laboratories</i></p> <p>Bill Rosen <i>Executive Director eHealth Policy and Standards Pfizer Global R &amp; D</i></p>	<p>1:40 p.m. – 2:25 p.m.</p> <p>(45 min.)</p>
	<p>John Rapoza, M.S., R.Ph. <i>CEO JRRapoza Associates, Inc.</i></p> <p>Ari Kaliannan <i>Chief Executive Member Newtech Global Solutions, LLC</i></p>	<p>2:25 p.m. – 2:40 p.m.</p> <p>(15 min.)</p>
<b>Break</b>		2:40 p.m. – 2:50 p.m.
	<p>Mark Rutkiewicz <i>Director, Quality Assurance AGA Medical</i></p>	<p>2:50 p.m. – 3:20 p.m.</p> <p>(30 min.)</p>

	<p>Jason Rock  <i>CIO</i>  <i>Global Submit, Inc.</i></p>	<p>3:20 p.m. – 3:50 p.m.  (30 min.)</p>
	<p>Laurie Rose  <i>Director, Product Management</i>  <i>SAS</i></p>	<p>3:50 p.m. – 4:20 p.m.  (30 min.)</p>
	<p>Terence R. Zagar  <i>Chief Technologist</i>  <i>Northrop Grumman Information</i>  <i>Technology</i>  <i>Health Solutions/Life Science</i></p>	<p>4:20 p.m. – 4:50 p.m.  (30 min.)</p>

\*\*Time is an approximation