



**Seroquel USPT Meeting Minutes  
May 10, 2000**

**Attendees:** Brain Ault, Kendra Baker, Don Beamish, Mike Czupryna, Deni Deasy, Jim Eash, Scott French, Jeff Goldstein, Michael Hickey, Steve Koelsch, Gerald Limp, Jamie Mullen, Mike Murray, Fred Nicklas, Georgia Tugend, Paul Yueng

**Apologies:** Shawn O'Brien

**Decisions/Discussion Points**

- Ad Hoc team to be formed to deal with FDA letter re: HTG & diabetes. Team leader: Gerald Limp. Team members: Martin Jones, Martin Brecher, Paul Duffy, Vikram Dev, Jamie Mullen, Ihor Rak.
- The Clinical Development Plan for Seroquel was presented and agreement was reached on the ranking of the priority/projects. The budget for this plan will be developed in a rough version to be followed with a more precise version at a later date.
- The Lieberman trail proposal was approved as a 3-arm trial.
- The SR study options were reviewed. The USPT position was to recommend two studies: one for accelerated approval in the US and another for ROW needs that would include IR comparators.
- Granules should be moved to priority 2.
- Although it is recognized that a more restrictive label may be imposed for Seroquel, there will be no change to the elderly promotional strategy at this time.

**ACTIONS**

	<b>Description</b>	<b>Responsibility</b>	<b>Target Date</b>
1	Recommendation for SOP safety reports presented. Overall review and sign-off to be obtained. Communication of change to affected groups	Scott French Brian Ault	4/30/00*
2	Forward copies of Dan Cushing's slides to team	Don Beamish	5/15/00
3	Present IIT process for sales representatives to the team	Jamie Mullen	6/6/00
4	CDP budge preparation: rough cut final version	Brian Ault "	6/15/00 7/15/00
5	Nick Troise to be advised of USPT position to continue elderly promotional strategy.	Gerald Limp	6/1/00
6	Product Operating Team minutes and agendas to be circulated to the USPT.	Team Leaders	ongoing
7	Operating team membership to be reviewed and changes noted and circulated to USPT.	Team Leaders	6/1/00