

GSK MenHiberix BLA Committee Email, August 05, 2011 - MenHiberix

From: Bridgewater, Jennifer
Sent: Friday, August 05, 2011 3:50 PM
To: Prutzman, Kirk C; Temenak, Joseph; Staten, David; Dickerson, David
Cc: Lynn, Freyja; Slater, Jay; Bridgewater, Jennifer
Subject: GSK MenHiberix BLA Committee, STN125363
Hi all -

Freyja has returned to DBPAP after a time at a NIH. Her speciality is serology and we want her on board this file to work on serology. So we are asking you to please add her formally as a committee member, job type, CMC, serology.

David D - is there anything you need to do to make sure she can physically access the file in the EDR? She is able to be added to any committees as we filled out the DCC-101. If you need to do anything special so the BLA shows up in her workload and she can access it please do.

Thanks very much everyone -

Jen

Review Assignment	Committee Member	Supervisor
Chair	Joseph Temenak	Elizabeth Sutkowski
RPM	David Staten	Elizabeth Sutkowski
RPM	Kirk Prutzman	Elizabeth Sutkowski
Clinical Reviewer Lee	Meghan Ferris	Lucia
Product CMC/Serology Vann	Mustafa Akkoyunlu	Willie
Product CMC Slater	Willie Vann	Jay
Product CMC	Daron Freedberg	Willie Vann
Product CMC Slater	Drusilla L Burns	Jay
Product CMC	Annisa Cheung	
Product CMC	James E Keller	Drusilla Burns
Product CMC	Majid Laassri	Konstantin Chumakov
Product CMC	Steven A Rubin	Konstantin Chumakov
Product CMC	Michael Schmitt	
Product CMC	Shuang Tang	Philip Krause
Product CMC	Iryna Zubkova	
Product CMC	Freyja Lynn	
Toxicology	Steven C Kunder	David Green
Product CMC Slater	Tina Roecklein	Jay
Facilities/DMPQ Renshaw	Sean Byrd	Carolyn
Advertising/ Promotional Labeling Stockbridge	Maryann Gallagher	Lisa
Clinical Statistical Reviewer	Barbara Kransnicka	Dale Horne
Assays Statistical Reviewer	Tsai-Lien Lin	Dale Horne
Epidemiology	Manette Niu	Thomas Buttolph
DPQ/Lot Testing Plan	Rajesh Gupta	Bill McCormick
DPQ/Lot Testing Plan	Karen Campbell	Bill McCormick
Lot Release	Joe Quander	Jay Elterman
BiMo	Soloman Yimam	Patricia Holobaugh
Electronic Integrity Review	David Schwab	Laraine Henchal