REGULATORY ACTIVITY

07/23/86 -	LY170053 Original IND Submission
06/05/87 -	Mr. Richard Potter (FDA) called to obtain information on LY170053 for new IND data base that is being set up. He requested to know: (a) is drug marketed OUS? (b) number of human subjects exposed to the drug (c) number of deaths reported for subjects receiving the drug.
06/11/87 -	Submitted letter responding to Mr. Potter's questions of 6/5/87.
07/24/87 -	Annual Report
07/19/88 -	Annual Report
05/17/89 -	Submitted Tox Report Nos. 23, 24, & 25.
06/19/89 -	Submitted Tox Report No. 26.
07/18/89 -	Annual Report
02/21/90 -	NTF - Dr. Wheadon and Dr. Laughren (FDA) discussed schizophrenia trials.
07/16/90 -	Annual Report
07/16/90 -	Annual Report
08/17/90 -	Telephone conversation between CSO Sharon Norris and Al Webber regarding meeting
10/03/90 -	Submitted Protocols HGAE & HGAF.
11/19/90 -	NTF re: 11/26/90 call from Dr. Sathe regarding HGAE & HGAF
01/30/91 -	Submitted meeting request.
02/05/91 -	Submitted CIB.
02/05/91 -	Sharon Norris called to offer meeting date.
02/08/91 -	Submitted Protocol HGAG.
03/01/91 -	Submitted summary of Tox Report (3-Month Mice).
03/06/91 -	Al Webber called Sharon Norris (FDA) regarding meeting plans.
03/11/91 -	Submitted Protocol HGAH.
03/12/91 -	Submitted confirmation of meeting on March 21.
03/19/91 -	Sharon Norris called Al Webber with questions (for meeting).
03/21/91 -	Meeting with FDA
06/14/91 -	Submitted Tox Reports Nos. 30 & 31.
07/16/91 -	Submitted Protocol HGAD.
07/19/91 -	Annual Report
08/13/91 -	Submitted Protocol HCAI (^{14}C).
08/29/91 -	Dr. Earl Hearst (Medical Reviewer) called with questions on HGAI.
08/30/91 -	Submitted Final Report HGAE.
09/03/91 -	Submitted Tox Report No. 32.
11/18/91 -	Submitted amended Protocol HGAD.
12/23/91 -	Submitted HGAD addenda; generic name.
01/06/92 -	Sent interim analysis for Swedish authorities to FDA.
03/17/92 -	Submitted final report HGAH.
05/06/92 -	Submitted export authorization request.
05/14/92 -	Al Webber discussed Zyprexa with CSO Katurah Higgins.
06/18/92 -	Al Webber discussed Zyprexa with CSO Katurah Higgins.

07/13/92 -	Michelle Limoli called Al Webber with export authorization approval.
07/20/92 -	Annual Report
07/21/92 -	Received Australia export authorization.
11/09/92 -	Submitted HGAD addendum
11/10/92 -	FDA sent comments on Protocol HGAH.
11/16/92 -	Dr. Zerbe discussed DMB with Tom Laughren (FDA).
11/17/92 -	Al Webber discussed interim analysis submission with CSO Steve Hardeman.
12/22/92 -	Submitted interim analyses (HGAD & E003) and meeting request.
01/04/93 -	Al Webber discussed 12/22/92 submission with CSO Steve Hardeman.
01/06/93 -	Al Webber confirmed March 1, 1993 meeting date with CSO.
02/03/93 -	FDA sent permission to enroll women of childbearing potential.
02/22/93 -	Submitted "briefing document" for March 1, 1993 meeting.
02/23/93 -	Submitted intentions regarding blister packs.
03/01/93 -	End of Phase II meeting
03/08/93 -	Submitted revised CIB.
03/12/93 -	Submitted Protocol HGAJ.
03/18/93 -	Submitted Tox Report No. 36 and Protocol HGAM.
04/07/93 -	Submitted Protocol HGAQ
04/13/93 -	Submitted Protocol HGAP.
05/06/93 -	Faxed document to FDA toxicologist
05/10/93 -	CSO Steve Hardeman called Al Webber regarding Tox fax
05/20/93 -	Submitted Tox Report No. 37.
05/27/93 -	Submitted May 6, 1993 fax .
06/16/93 -	Telephone conversation: Gary Tollefson and Tom Laughren (FDA) regarding unblinded data to Eur. Ethical Review Committees
06/22/93 -	Submitted Protocol HGAN.
07/19/93 -	Annual Report
07/21/93 -	Submitted Protocol HGAT.
08/06/93 -	Submitted ADME Reports Nos. 1 and 2.
08/10/93 -	Submitted revised CIB.
08/24/93 -	NTF re:Al Webber discussed CRFs in NDAs with CSO Paul David
08/26/93 -	Letter to Tom Laughren regarding unblinding (Note to File)
09/07/93 -	FDA letter on HGA
09/08/93 -	NTF re: Todd Sanger called FDA Stat. Group Ed Nevius regarding statistical CANDA
09/09/93 -	NTF re: Al Webber called CSO Steve Hardeman
09/15/93 -	NTF re: Todd Sanger called FDA statistician David Hoberman
09/22/93 -	NTF re: Al Webber called CSO Robbin Nighswander regarding CANDA
09/22/93 -	Submitted protocol HGAV.
10/19/93 -	Eli Lilly and Company response to September 7, 1993 letter
10/21/93 -	FDA letter on HGAV
10/25/93 -	Alert call (Note to File)

11/12/93 -	Statistical Note to File (Sanger)
11/12/93 -	Submitted correction to Annual Report.
11/15/93 -	Submitted clarification of HGAD Canadian site addendum.
11/24/93 -	Submitted IND Safety Report (Dog Hematology).
11/29/93 -	Alert call to CSO (US93113121A) by Anita Clark
11/30/93 -	Alert call to CSO (SW93112848A) by Anita Clark
12/06/93 -	Submitted General Pharm. Report No. 1.
12/07/93 -	NTF re: CM&C teleconference with Stan Blum
12/09/93 -	Sent Drs. Leber and Laughren ACNP slide copy.
12/13/93 -	Submitted Protocol HGAU.
12/16/93 -	HGAJ amendment and clarification (regarding remoxipride)
01/11/94 -	Telephone conversation between CSO Steve Hardeman and Al Webber
01/25/94 -	M&C meeting at FDA (Note to File)
02/01/94 -	IND Safety Report - mice (convulsive threshold).
02/03/94 -	Submitted revised p. 10 for Tox Report No. 35.
02/04/94 -	Submitted General Pharm. Report No. 2.
02/07/94 -	Submitted corrections to HGAJ(a) & (b).
02/10/94 -	Alert call: US94021837A
02/11/94 -	Submitted Tox Report No. 39.
02/15/94 -	IND Safety Report - mice (lymphosarcomas)
02/16/94 -	Submitted correction of p. 23, Tox Report No. 15
02/16/94 -	Telephone conversation between CSO Robbin Nighswander and Al Webber
03/02/94 -	Alert call: US94024219A
03/02/94 -	Submitted Tox Report No. 42.
03/03/94 -	Submitted CIB
03/09/94 -	Telephone conversation between CSO Robbin Nighswander and Bob Hizer
03/10/94 -	Alert call: FN93041786A
03/10/94 -	Submitted Tox Report No. 43.
03/14/94 -	Submitted Tox Report No. 44.
03/15/94 -	Submitted Tox Report No. 24 and Protocol HGAO.
03/28/94 -	Submitted Protocol HGBA.
04/19/94 -	Al Webber discussed pre-NDA meeting with CSO Steve Hardeman.
04/20/94 -	Submitted ADME Report No. 25.
05/19/94 -	Submitted revised CIB
05/23/94 -	Submitted HGBE
05/24/94 -	Telephone conversation between CSO Steve Hardeman and Al Webber
06/15/94 -	Zyprexa discussion with CSO Paul David
06/09/94 -	MRO Earl Hearst talked with Charlie Haddad
06/20/94 -	Submitted ADME Report Nos. 3, 5, 6, 7, 12, 13, 14, 16, & 20
06/23/94 -	Sent CANDA meeting request
06/23/94 -	Sent letter requesting CANDA meeting.
06/29/94 -	Sent minutes of January 25, 1994 M&C meeting with FDA.

07/14/94 -	Submitted Tox Report No. 45
07/20/94 -	Annual Report
07/22/94 -	Telephone discussions with MRO Earl Hearst regarding safety
08/05/94 -	Prolactin-related information report
08/05/94 -	Dr. Hearst and Charlie Haddad discussed CANDA.
08/05/94 -	Received fax of templates for tables from MRO Dr. Earl Hearst.
08/12/94 -	IND Safety Report - Hematology (Dogs)
08/25/94 -	Submitted revised pages for Tox Report No. 42.
08/29/94 -	3-day alert (US94081489A)
09/08/94 -	Dr. Baweja and Rich Bergstrom discussed bioequivalence study.
09/09/94 -	Letter to Dr. Peter Holland regarding publicity.
09/15/94 -	Submitted revised CIB.
09/15/94 -	Sent Dr. Baweja bioequivalence study plan.
09/22/94 -	3-day alert (US94092602A)
09/22/94 -	Sent U.K. export authorization request.
09/28/94 -	Telephone discussion between Dr. Beasley and Dr. Hearst (two calls).
09/29/94 -	Telephone discussion between Dr. Beasley and Dr. Hearst (two calls).
09/29/94 -	Submitted Protocol HGAX.
10/05/94 -	Submitted Tox Reports Nos. 50 & 51.
10/05/94 -	CSO Robbin Nighswander and Al Webber discussed CANDA meeting.
10/10/94 -	Submitted Protocol HGBI.
10/11/94 -	CSO Steve Hardeman and Al Webber discussed CANDA meeting.
10/17/94 -	Todd Sanger spoke with Dr. Nevius regarding pre-NDA meeting.
10/25/94 -	Sent letter confirming CANDA meeting.
10/28/94 -	Dr. Baweja and Rich Bergstrom discussed bioequivalence study.
10/28/94 -	Submitted Protocol HGBX, ADME Reports 8, 19, & 29.
10/28/94 -	FDA approved IAS-D-94-9-56 (U.K.).
11/01/94 -	FDA written "coaching" on draft labeling received.
11/01/94 -	NTF re: "fax" issues.
11/01/94 -	CANDA meeting.
11/01/94 -	NTF re: CANDA meeting.
11/07/94 -	Al Webber spoke with CSO Steve Hardeman.
11/09/94 -	Fax to CSO Steve Hardeman in preparation for call to Dr. Laughren.
11/11/94 -	Requested pre-NDA meeting (included briefing document).
11/14/94 -	Call to FDA regarding discussion with Dr. Laughren.
11/19/94 -	Call to Al Webber with 2/16/95 date for pre-NDA meeting.
11/21/94 -	Conference call with Dr. Laughren.
11/21/94 -	Clinical Section of NDA guidance faxed to Gary Tollefson by CSO Steve Hardeman.
11/22/94 -	Submitted Protocol HGCA.
12/01/94 -	Letter to FDA regarding Dr. Garver.
12/02/94 -	Submitted revised CIB.
12/07/94 -	Submitted Protocol HGAW and HGBY.

12/12/94 -	Comment on start of HGAW and HGBY.
12/12/94 -	Al Webber called CSO Steve Hardeman regarding HGAW and HGBY.
12/14/94 -	Submitted Protocol HGBG.
12/19/94 -	IND Safety Report - dog hepatic amyloidosis
12/22/94 -	Three day alert call (Haldo - US93110097A).
01/09/95 -	Three day alert call (US94123868A).
01/06/95 -	Submitted notes to reviewer regarding Tox Reports 15, 16 & 22.
01/13/95 -	Call between CSO Steve Hardeman and Al Webber.
01/26/95 -	Todd Sanger discussed pre-NDA meeting with Ed Nevius (FDA).
02/03/95 -	Todd Sanger discussed pre-NDA meeting with David Hoberman (FDA).
02/09/95 -	Submitted confirmation of 2/16/95 meeting and other issues.
02/13/95 -	Dr. Hossain called regarding HGBY.
02/15/95 -	CSO Steve Hardeman and Al Webber discussed pre-NDA meeting.
02/16/95 -	Pre-NDA meeting.
02/17/95 -	Submitted revised CIB.
02/22/95 -	M&C amendment (sent to 12,274 by mistake)
02/24/95 -	Sent letter correcting February 22, 1995 mistake.
02/24/95 -	Annual Report
02/27/95 -	Al Webber obtained NDA # (20-592) and User Fee #(2756).
02/28/95 -	Submitted Protocol HGCB
03/10/95 -	Dr. Hossain called Al Webber regarding HGCB.
03/14/95 -	Dr. Hossain called Rich Bergstrom.
03/14/95 -	CSO Steve Hardeman called Al Webber.
03/15/95 -	Submitted request for waiver of paper CRFs.
03/27/95 -	Al Webber called CSO Steve Hardeman regarding contact with Dr. Laughren.
04/13/95 -	Requested waiver of case report tabulations.
04/13/95 -	Submitted revised CIB.
04/18/95 -	Fax from CSO Steve Hardeman regarding biopharm.
04/20/95 -	Submitted final report for study HGAV and non-clinical pharmacy report No. CNS66 - CNS70.
05/03/95 -	FDA letter granting two waiver requests
05/04/95 -	Submitted two addenda for HGAJ.
05/04/95 -	Fax of lab values issues to CSO Steve Hardeman
05/08/95 -	Three-day alert call: F1D-MC-HGBH 325 3251
05/08/95 -	FDA comment on HGCB
05/10/95 -	Submitted revisions to Tox Report No. 42 and ADME Report No. 5.
05/11/95 -	CSO Steve Hardeman called to agree with 5/4/95 fax recommendations.
05/17/95 -	Submitted revision to Tox Report No. 44.
05/20/95 -	Submitted protocol HGCG.
05/31/95 -	Letter to FDA regarding electronic submission of oncogenic studies from Ken Carlson
06/09/95 -	Conference call with Dr. Baweja regarding 15 mg tablet

06/12/95 - Al Webber discussed several issues with CSO Steve Hardeman.
06/15/95 - Letter to Dr. Baweja regarding 15 mg tablets
06/15/95 - Sent correction of Tox Report No. 49.
06/21/95 - Al Webber spoke with CSO Steve Hardeman regarding two NDAs.
07/05/95 - Sent letter iterating reports not submitted.
07/07/95 - Al Webber spoke with CSO Steve Hardeman regarding two NDAs.
07/12/95 - Call from Tom Laughren (FDA) to Al Webber
07/13/95 - Conference call with Tom Laughren
07/17/95 - Sent correction of Tox Report No. 49.
07/17/95 - Submitted list of study reports NOT submitted to IND.
07/19/95 - Conference call with Tom Laughren
07/20/95 - Federal Express of safety document to Tom Laughren (FDA)
07/20/95 - Federal Express of efficacy document to Tom Laughren (FDA)
07/21/95 - Annual Report
08/02/95 - Conference call with Tom Laughren
08/09/95 - Submitted protocol HGCS.
08/11/95 - Adverse event listings sent to Dr. Laughren.
08/14/95 - WP 6.1 formatting sent to Dr. Laughren.
08/15/95 - ISS draft sent to Dr. Laughren.
08/23/95 - Call from Al Webber to Dr. Laughren, returned to Dr. Beasley, and followed by fax to Al Webber
08/24/95 - Export Auth. approval for Mexico
08/25/95 - Fax to CSO Steve Hardeman re: location of items in FDA NDA worksheet
08/25/95 - Three-day alert (FR95043187A)
08/28/95 - Submitted revised CIB.
08/29/95 - Todd Sanger discussed Stat review by Dr. David Hoberman.
08/30/95 - Conference call re: 8/25 fax
08/31/95 - Three-day alert (NL95061522A)
09/01/95 - Sent efficacy analyses to Dr. Laughren.
09/08/95 - Submitted non-reference request for Dr. Tommingo.
09/08/95 - Call from Al Webber to FDA re: granule NDA
09/11/95 - NTF re: study HGAE
09/11/95 - Submitted amended final pk report for study HGAE.
09/11/95 - Submitted additional list of study reports NOT submitted to IND.
09/12/95 - Al Webber called CSO Steve Hardeman.
09/12/95 - Sent bibliography to Dr. Laughren.
09/14/95 - Charlie Haddad discussed CANDA with Dr. Andreason.
09/20/95 - Al Webber called CSO Steve Hardeman.
09/21/95 - 20-592 - NDA submitted.
09/21/95 - 20-592 - Rick Bergstrom called Dr. Hossain re: biopharm. review.
09/22/95 - 20-592 - Letter to David Mon re: electronic presentation of data
09/25/95 - 20-592 - Note to File re: patient enrollment information handed to CSO Steve Hardeman on 9/25/95
09/25/95 - 20-592 - Charlie Haddad and Al Webber met with CSO Steve Hardeman.

09/25/95 - 20-592 - Letter to FDA Detroit Field Office
09/27/95 - 20-592 - Charlie Haddad discussed CANDA with Dr. Andreason.
09/27/95 - 20-592 - CSO Steve Hardeman called Al Webber re: 4-mo. safety update.
09/28/95 - Three-day alert (TP95091135A).
09/28/95 - Response to some questions from 8/30 conference call
09/29/95 - 20-592 - Letter from FDA acknowledging receipt of NDA on 9/22/95
10/02/95 - 20-592 - CSO Steve Hardeman called Al Webber re: NDA Vol. 30, 33, and 72 for tox review.
10/02/95 - 20-592 - Submitted letter to NDA re: David Moss letter.
10/02/95 - 20-592 - FDA letter re: four-month safety update
10/03/95 - 20-592 - Submitted rodent oncogenic data on diskette.
10/04/95 - 20-592 - Submitted diskette for stat reviewer.
10/06/95 - 28,705 - Three-day alert (HGAJ-322-3008)
10/11/95 - 20-592 - CSO Steve Hardeman called Al Webber re: request for EA and Vol. 242.
10/11/95 - 20-592 - Charlie Haddad, Mark Ciresi, Chris Barnes, and Al Webber visited Neuropharm. Div. and installed software
10/11/95 - 28,705 - Three-day alert (US95080568A)
10/12/95 - 20-592 - CSO Steve Hardeman called Al Webber re: Biopharm. and Tox. reviewers.
10/16/95 - 20-592 - Call from CSO Steve Hardeman to Al Webber re: WP 6.1 diskette of ISE Attachment #2
10/17/95 - 28,705 - CSO Steve Hardeman called Al Webber re: HGBG (b) (4).
10/18/95 - 20-592 - NTF re: WP 6.1 diskette containing ISE Attachment #2
10/18/95 - 20-592 - Sent WP diskette containing ISE Att. 2 to CSO Steve Hardeman.
10/19/95 - 20-592 - Submitted electronic version of paper NDA on three diskettes.
10/24/95 - 20-592 - CSO Steve Hardeman requested desk copies of NDA Vol. 1.117-1.121.
10/27/95 - 28,705 - Submitted CNS110, CNS111, ADME Rpt. No. 57
10/31/95 - 20-592 - Submitted correction of typos in Item 6.
11/06/95 - 28,705 - Requested withdrawal of HGBG (b) (4).
11/08/95 - 20-592 - Submitted November 6 letter to David Mon.
11/13/95 - 20-592 - Telephone conversation between Ann Marie Crawford and MRO Paul Andreason
11/15/95 - 28,705 - Al Webber and CSO Steve Hardeman discussed I.M. IND and bipolar study.
11/15/95 - 20-592 - MRO Paul Andreason provided question via voicemail -- responded to on same day.
11/16/95 - 20-592 - Submitted correction to typos in annotated draft labeling.
11/17/95 - 20-592 - Submitted protocol HGCY.
11/17/95 - 20-592 - FDA statistician Dr. David Hoberman called Al Webber with question on HGAP.

11/17/95 - 20-592 - Robert Young (FDA Compliance Div.) called Al Webber with several requests.

11/20/95 - 20-592 - Information sent to Robert Young, FDA Compliance Div.

11/20/95 - 20-592 - Sent Dr. Andreason WP 6.1 diskette and hard copy of ISS Att. 2.

11/20/95 - 20-592 - Todd Sanger and Charles Beasley called David Hoberman re: his November 17 question.

11/20/95 - 20-592 - Submitted Tox. Rpt. No. 67 (2-yr. mouse).

11/22/95 - 20-592 - Al Webber and CSO Steve Hardeman discussed several issues.

11/22/95 - 20-592 - Dr. Andreason called Al Webber with question regarding CANDA browser; Mark Ciresi responded that day.

11/27/95 - 20-592 - Robert Young (FDA Compliance Div.) called with several questions.

12/01/95 - 28,705 - Three-day alert (US595114204A)

12/04/95 - 20-592 - Submitted information sent to Dr. Hossain on November 28.

12/06/95 - 28,705 - Submitted protocol HGDI, ADME Rpt. No. 58, Tox. Rpt. No. 66.

12/07/95 - 20-592 - Information sent to Robert Young in response to his November 27 request.

12/08/95 - 28,705 - Submitted protocol HGCT.

12/15/95 - 20-592 - Submitted information sent to Dr. Harris on December 7.

12/20/95 - 20-592 - Letter faxed to MRO Dr. Andreason.

12/20/95 - 20-592 - Fax of question from MRO Dr. Andreason to Charles Beasley.

12/21/95 - 28,705 - Submitted protocol HGCR

01/15/96 - 20-592 - Sent diskette and 1-page description of files re: 2-year mouse study to Steve Hardeman.

01/16/96 - 20-592 - Fax of tox question from CSO to Al Webber

01/17/96 - 20-592 - Dr. Andreason called Al Webber with question.

01/17/96 - 20-592 - Fax of tox question from CSO to Al Webber

01/17/96 - 20-592 - Conference call with Dr. Andreason re: question earlier in day

01/18/96 - 20-592 - Telephone discussion on trade name: Al Webber and CSO Steve Hardeman

01/18/96 - 20-592 - Cheryl Fanning spoke with CM&C reviewer, Dr. Mona Zarifa.

01/25/96 - 20-592 - Telephone discussion on CM&C meeting: Al Webber and CSO Steve Hardeman

01/25/96 - 29-592 - Submitted response to 1/17/96 tox question.

01/25/96 - 20-592 - Telephone discussion of trade name: Al Webber and CSO Steve Hardeman

01/28/96 - 20-592 - Submitted response to 1/16/96 tox question.

01/29/96 - 20-592 - Submitted CM&C information requested by Dr. Zarifa on 1/22/96

02/01/96 - 20-592 - Submitted response to 1/26/96 Biopharm. question.

02/14/96 - 20-592 - Dr. Laughren told Charles Beasley: No Adv. Con't. Review.

02/20/96 - 20-592 - Gerry Long spoke with Biometrics reviewer Roswitha Kelley.
02/23/96 - 20-592 - Telephone discussion: Al Webber and CSO Steve Hardeman
02/23/96 - 20-592 - Al Webber discussed trade name with Nomenclature Com't Chair Dan Boring.
02/23/96 - 20-592 - Al Webber called Dan Boring re: trade name.
03/01/96 - 28,705 - Cross reference letter for Dr. Potkin
03/04/96 - 20-592 - Al Webber informed of no April 22-23 Adv. Con't. Mtg.
03/04/96 - 20-592 - Questions from and response to Dr. Andreason via telephone
03/07/96 - Submitted revised CIB.
03/14/96 - Telephone conversation between Cheryl Fanning and chem. reviewer Dr. Mora Zarifa
03/19/96 - MRO Paul Andreason called Al Webber
03/21/96 - Submitted CM&C info.
03/26/96 - Fax of trademark perspective to CSO Steve Hardeman
04/03/96 - 20-592 - Letter from FDA re: trade name
04/17/96 - 20-592 - Submitted revised trademark.
04/24/96 - Submitted addendum to Tox Rpt. No. 54.
04/25/96 - Al Webber discussed several issues with CSO Steve Hardeman.
04/26/96 - Submitted ADME Rpt. No. 60.
05/01/96 - Submitted protocol HGDY.
05/02/96 - CSO Steve Hardeman requested diskette with Tox Rpt. #67 data. Sent same day.
05/03/96 - Submitted revised CIB.
05/08/96 - 20-592 - Question from MRO Paul Andreason. Answered by fax on 5/13
05/10/96 - Telephone discussion: Al Webber and Dan Boring
05/13/96 - FDA letter with CM&C question
05/20/96 - Dr. Dubitski (FDA) called Charles Beasley.
05/20/96 - Diskette send to MRO Paul Andreason.
05/21/96 - Trade name conversations among Al Webber, Steve Hardeman, and Dan Boring
05/22/96 - Al Webber discussed several issues with CSO Steve Hardeman.
05/22/96 - Submitted additional pages for Tox Rpt. No. 42.
05/22/96 - 20-592 - Al Webber spoke with CSO Steve Hardeman re: trade name
05/23/96 - 20-592 - Telephone call between Charles Beasley and Paul Andreason
05/27/96 - 20-592 - Case summaries provided to MRO Paul Andreason by Charles Beasley
05/28/96 - 20-592 - Al Webber spoke with Dan Boring (FDA) re: trade name
06/11/96 - 20-592 - Fax from FDA re: EA deficiencies
06/12/96 - Fax from FDA re: tox.
06/12/96 - Fax to FDA re: 6/12 request
06/19/96 - Sent clinical dev. plan for SAIM to Dr. Leber
06/27/96 - 20-592 - Dr. Dubitsky (FDA) called Charles Beasley with a question
06/27/96 - 20-592 - Al Webber called CSO Steve Hardeman re: Dr. Borison

06/27/96 - 28,705 - Letter to FDA re: Borison
07/12/96 - 28,705 - Letter to FDA re: Borison's results
07/17/96 - 28,705 - MRO Paul Andreason called Al Webber re: HGET Annual Report
07/18/96 -
07/19/96 - 20-592 - MRO Paul Andreason called to request list of all submissions to NDA (faxed format to Al Webber)
07/22/96 - 20-592 - Letter to FDA responding to their fax on 6/11 re: EA deficiencies
07/23/96 - 20-592 - Log of written commumications to FDA faxed to Dr. Andreason (FDA)
07/23/96 - 20-592 - Fax of document to Dr. Andreason (FDA) in response to his requests
07/23/96 - 20-592 - MRO Paul Andreason called Charles Beasley
07/24/96 - 20-592 - MRO Paul Andreason called Jeff Ramsey with questions
07/25/96 - 20-592 - MRO Paul Andreason called Jeff Ramsey with questions
07/26/96 - 20-592 - Ann Marie Crawford and Jeff Ramsey called MRO Paul Andreason regarding 7/25 question
07/26/96 - 20-592 - Submitted carton and container labels
07/26/96 - 28,705 - Submitted ADME Rpt. No. 59, Nonclin. Pharm. CNS151, Tox Rpt. No. 71
07/29/96 - 20-592 - MRO Paul Andreason called Jeff Ramsey with questions
08/01/96 - 28,705 - Submitted protocol HGEB
08/02/96 - 28,705 - Submitted protocol HGEX
08/02/96 - 20-592 - Telephone discussion between Al Webber and CSO Steve Hardeman
08/07/96 - 28,705 - Sent page # corrections; Protocols HGEV and HGDG
08/13/96 - 28,705 - Submitted revised CIB
08/21/96 - 28,705 - Submitted final report HGAO

Redacted

08/30/96 - 20-592 - Date of approvable letter
09/03/96 - 20-592 - FDA faxed approvable letter to Al Webber
09/04/96 - 20-592 - Submitted intention to respond to approvable letter
09/05/96 - 20-592 - Robert Young (FDA) called Al Webber with questions about Dr. Green
09/05/96 - 51,457 - FDA sent acknowledgement of IND submission
09/06/96 - 20-592 - Jo Chapman (Lilly Rockville office) delivered document for Dr.Laughren
09/09/96 - 28,705 - Submitted protocol HGEC
09/09/96 - 20-592 - Submitted document provided to Dr. Laughren on 9/6
09/09/96 - 20-592 - Fax to CSO Steve Hardeman re: draft labeling
09/09/96 - 20-592 - Telephone discussion between Rich Bergstrom and Dr. Baweja (FDA)
09/10/96 - 20-592 - Al Webber called CSO Steve Hardeman re: some issues in draft labeling
09/11/96 - 20-592 - CSO Steve Hardeman called Al Webber re: draft labeling

09/12/96 - 20-592 - Telephone conversation between Rich Bergstrom and Dr. Baweja (FDA)
09/13/96 - 51,457 - MRO Paul Andreason called Greg Brophy with questions. Response fax on same day
09/13/96 - 20-592 - Dr. Baweja (FDA) called Rich Bergstrom
09/16/96 - 20-592 - Cheryl Fanning spoke with Dr. Zarifa re: How Supplied Section of labeling
09/16/96 - 20-592 - Submitted response to approvable letter
09/17/96 - 20-597 - Al Webber received fax from CSO Steve Hardeman re: pharmacology information in labeling
09/17/96 - 20-592 - Conference call on draft labeling
09/18/96 - 20-592 - Fax to Dr. Laughren (FDA); received by him early on 9/19
09/18/96 - 20-592 - Conference call with FDA on labeling
09/18/96 - 20-592 - Fax to CSO Steve Hardeman re: toxicology information in labeling
09/18/96 - 20-592 - Fax to CSO Steve Hardeman re: How Supplied Section of labeling
09/18/96 - 20-592 - Fax from CSO Steve Hardeman to Al Webber re: carcinogenesis portion of draft label
09/19/96 - 20-592 - Al Webber faxed CSO Steve Hardeman corrected copy of 9/18 for Dr. Laughren
09/20/96 - 20-592 - Fax to CSO Steve Hardeman carcinogenesis portion of draft labeling
09/20/96 - 20-592 - Al Webber faxed CSO Steve Hardeman minor editorial changes to draft labeling
09/23/96 - 20-592 - Al Webber faxed CSO Steve Hardeman correction of Animal Toxicology Section
09/23/96 - 20-592 - Second of two tox-related faxes to CSO Steve Hardeman
09/23/96 - 20-592 - C. Perry sent CSO Steve Hardeman copy of promotional materials
09/24/96 - 20-592 - Note to file regarding telephone conversation on labeling
09/25/96 - 20-592 - Submission of addendum to safety update
09/25/96 - 51,457 - Proj. Man. Katurah Higgins called Al Webber to say we may proceed
09/30/96 - 20-592 - APPROVAL
10/11/96 - 20-592 - Submitted FPL per 9/30 request
10/11/96 - 28,705 - Submitted cross-reference letter for Dr. Potkin
10/15/96 - 28,705 - Submitted protocol HGEH (bipolar mania)
10/15/96 - 28-705 - Al Webber discussed bipolar disorder with Proj. Man. Steve Hardeman
10/17/96 - 51,457 - MRO Paul Andreason requested info regarding assessment of behavioral changes
10/17/96 - 28,705 - Submitted reiteration of allocation of investigators for HGEH
10/21/96 - 51,457 - Response to 10/17 request
11/01/96 - 28,705 - Submitted cross-reference letter for Dr. Kowatch
11/05/96 - 28,705 - MRO Paul Andreason called Al Webber re: HGEH

11/06/96 - 28,705 - Al Webber and Proj. Man. Steve Hardeman discussed short-acting I.M.

11/13/96 - 20-592 - Al Webber called Proj. Man. Steve Hardeman re: high-strength tablets

11/14/96 - 20-592 - Submitted pediatric labeling supplement

11/20/96 - 28,705 - Corrected error in S.N. 390

11/20/96 - 51,457 - Corrected error in IND submission

11/21/96 - 28,705 - Submitted revised CIB

11/22/96 - 20-592 - Submitted final study report HGAW (renal) (X-ref. 28,705)

11/22/96 - 28,705 - MRO Paul Andreason called re: HGEH

11/26/96 - 28,705 - MRO Paul Andreason and Al Webber discussed short-acting I.M. and Bipolar Disorder

12/02/96 - 28,705 - Conference call on short-acting I.M.

12/16/96 - 20-592 - Submitted packaging operations changes (S-001)

12/17/96 - 28,705 - Submitted HGEH investigator replacement of Tohen by Centorrino

12/17/96 - 28,705 - Al Webber and Proj. Man. Steve Hardeman discussed synchronization of annual reports

12/17/96 - 28,705 - Al Webber discussed Zydis plans with Proj. Man. Steve Hardeman

01/07/97 - 28,705 - Cross-reference letter for Dr. Green

01/10/97 - 28,705 - Zydis discussion between Cheryl Fanning and Stan Blum

01/13/97 - 28,705 - Submitted final study report HGAU

01/13/97 - 28,705 - Questions on PET study from MRO Paul Andreason

01/15/97 - 28,705 - Submitted Tox Rpt. 74

01/15/97 - 20-592 - CM&C discussion between Gerry Kirschner and Stan Blum

01/17/97 - 28,705 - Submitted protocol HGDH (First Episode)

01/20/97 - 28,705 - Fax re: Zydis to Proj. Man. Steve Hardeman

01/23/97 - SAIM letter sent to Dr. Andreason (Note to File in 28,705)

01/29/97 - 51,457 - IND response letter faxed to Al Webber by Katurah Higgins

01/29/97 - 51,457 - IND response letter

01/29/97 - 20-592 - Submitted PADER

02/03/97 - 28,705 - Fax to Steve Hardeman and discussions with Al Webber re: investigator-initiated studies

02/07/97 - 20-592 - Acknowledgement of FPL submission (10/11/96)

02/13/97 - 28,705 - Submitted final clinical study report HGCC

02/19/97 - 20-592 - Approval of S-001 (secondary packaging site)

02/20/97 - 28,705 - Submitted Bipolar Mania plans

02/24/97 - 28,705 - Cheryl Fanning and Stan Blum discussed Zydis formulation

02/24/97 - 20-592 - Al Webber discussed several issues with Steve Hardeman

02/24/97 - 28,705 - Submitted Clinical Study Report for Medical Resource Use for HGAJ

02/25/97 - 28,705 - Submitted HGDH (1)

02/2797 - 20-592 - Submitted Tardive Dyskinesia supplement (S-002)

03/12/97 - 20-592 - Telephone conversation: Steve Hardeman and Al Webber

03/14/97 - 20-592 – Submitted Patient Info (Orange Book related)

03/14/97 - 28,705 - Submitted Tox Rpt No 75 (IM)
03/17/97 - 20-592 - CM&C Supplement (S-003)
03/19/97 - 28,705 - Cross-reference letter for Dr. Robert Smith
03/20/97 - Submitted CIB update
03/20/97 - Zydis meeting with FDA; Bergstrom note to file
03/20/97 - NTF (dated 3/25) re: Rich Bergstrom's SAIM discussion with Dr. Baweja
03/20/97 - 28,705 - FDA meeting on Zydis formulation (NTF dated 7/25)
03/24/97 - 20-592 - FDA acknowledgement of S-003 (3/17/97)
Redacted
03/25/97 - 28,705 - SAIM telephone conversation between Al Webber and MRO and CSO
03/27/97 - 51,457 - Informed FDA of discontinuation of Dr. Shua-Haim
04/02/97 - 28,705 - CM&C Amendment
04/04/97 - 28,705 - Submitted revised ADME Rpt. No. 5
04/07/97 - 28,705 - Contact from Endocrine Div. CSO re: misdirected submission
04/14/97 - 28,705 - Submitted summary of SAIM status
04/14/97 - 20-592 - Submitted 15/20 mg supplement (S-004)
04/17/97 - 28,705 - Cross-reference letter for Dr. Townsend
04/18/97 - 20-592 - FDA sent approval of S-003(3/17/97)
04/18/97 - 20-592 - FDA acknowledgement of S-004 (4/14/97)
04/23/97 - 28,705 - Cross-reference letter for Dr. Kevin Blocks
04/28/97 - 20-592 - Al Webber and CSO Steve Hardeman discussed 2.5 mg tablet
04/29/97 - 28,705 - Al Webber faxed CT Safety Summary outline to CSO Steve Hardeman
04/29/97 - 20-592 - Submitted PADER
04/30/97 - 27,705 - Cross-reference letter for Dr. Ondo
04/30/97 - 28,705 - Cross-reference letter for Dr. Herz
04/30/97 - 28,705 - Cross-reference letter for Dr. Lieberman
04/30/97 - 20-592 - Letter to FDA re: 2.5 mg tablet
05/06/97 - 28,705 - Cross-reference letter for Dr. Donald Black
05/07/97 - 20-592 - Telephone conversation between Al Webber and CSO Steve Hardeman and also Dr. Andreason
05/07/97 - 20-592 - (NTF dated 5/16) Telephone conversation re: 2.5 mg tablets
05/08/97 - 28,705 - Submitted protocol HGGB (valproate interaction)
05/15/97 - 28,705 - Cross-reference letter for Dr. Bogenschutz
05/15/97 - 28,705 - Request for pre-NDA meeting on bipolar mania
05/20/97 - 28,705 - Submitted protocol HGFW
05/23/97 - 20-592 - Submitted PIEFR
05/27/97 - 28,705 - Cross-reference letter for Dr. Simpson
06/02/97 - 28,705 - CM&C Amendment
06/03/97 - 20-592 - David Barash (FDA) called re: PADER
06/11/97 - 28,705 - Cross-reference letter for Dr. Pappert

06/13/97 - 28,705 - Phase 4 Commitment response
06/25/97 - 20-592 - Pre-NDA meeting for bipolar mania
07/01/97 - 20-592 - Conference call on hematology case
07/09/97 - 28,705 - Cross-reference letter for Dr. Buccigross
07/09/97 - 28,705 - Project Manager Steve Hardeman called with Phase 4 comment
07/11/97 - 28,705 - Cross reference letter for Dr. Schulz
07/11/97 - 28,705 - Cross reference letter for Dr. Noyes
07/17/97 - 28,705 - Submitted new CIB
07/17/97 - 51,457 - Cross-reference of CIB
07/17/97 - 28,705 - Letter to FDA describing annual report timing

Redacted

07/30/97 - 28,705 - Submitted review of hematological adverse event reports
07/30/97 - PADER
07/31/97 - 28,705 - Cross-reference for Dr. Nelson
08/04/97 - 28,705 - Cross-reference letter for Dr. Howanitz
08/04/97 - 28,705 - Cross-reference letter for Dr. Malone
08/05/97 - 28,705 - Cross-reference letter for Dr. Kunik
08/05/97 - 20-592 & 28,705 - Telephone conversation between Gary Tollefson and Tom Laughren
08/13/97 - 20-592 - Rich Bergstrom discussed 15/20 mg tablets with Ray Baweja (FDA Biopharm. reviewer)
08/14/97 - 28,705 - Cross-reference letter for Dr. Verma
08/14/97 - 28,705 - Cross-reference letter for Dr. Hendren
08/14/97 - 28,705 - Al Webber discussed Zydis formulation with FDA Project Manager Steve Hardeman
08/22/97 - 20-592 - Submitted dissolution data for 15/20 mg tablets
08/25/97 - 28,705 - Cross-reference letter for Dr. Sanchez
08/27/97 - 28,705 - Cross-reference letter for Dr. Rosenbaum
09/04/97 - 28,705 - Cross-reference letter for Dr. Smelson
09/05/97 - 28,705 – NTF re: Gary Tollefson and Tom Laughren discussed psychotic depression (this discussion probably occurred 09/02/97)
09/08/97 - 28,705 - Cross-reference letter for Dr. Kravitz
09/09/97 - 28,705 - Cross-reference letter for Dr. Pico
09/09/97 - 20-592 - Approval of 15/20 mg tablets (S-004)
09/11/97 - 28,705 - Submitted HGFN (Antipypertensive agents) and HGGC (child and adolescent bipolar)
09/14/97 - 28,705 - Cross-reference letter for Dr. Tsuang

Redacted

09/23/97 - 28,705 - Gary Tolefson and Tom Laughren discussed HGEH results
09/24/97 - 20-592 - CM&C submission (S-005)
09/29/97 - 28,705 - Al Webber and Project Manager Steve Hardeman discussed independent IND process
10/06/97 - 28,705 - Cross-reference letter for Dr. Hicklin
10/06/97 - 28,705 - Cross-reference letter for Dr. Smith

10/06/97 - 28,705 - Al Webber discussed several issues with Proj. Mgr. Steve Hardeman
10/14/97 - 28,705 - Cross-reference letter for Dr. Hutchison
10/23/97 - 28,705 - Request for Zydis pre-NDA meeting
10/27/97 - 28,705 - MRO Paul Andreason called with question on HGGF
10/29/97 - 28,705 - ADME Rpt. No. 68
10/29/97 - PADER
11/17/97 - 20-592 - Conversations on fees for bipolar eff. suppl.
11/19/97 - 28,705 - Abbrev. Final Rpt. HGBS
11/27/97 - 28,705 - Cross-reference letter for Dr. Quintana
12/02/97 - 20-592 - MRO Paul Andreason called with several questions related to EKGs
12/03/97 - 20-592 - Submission of bipolar mania supplement (S-006)
12/04/97 - 20-592 - CSO Melina Mallandrucco was sent information (CD-ROM of 12/3 info)
12/04/97 - 20-592 – Approval of S-005
12/12/97 - Annual Report
12/15/97 - 28,705 - Cross-reference letter for Dr. Degen
12/17/97 - 28,705 - Submitted protocol HGGW
12/19/97 - 20-592 – CM&C Supplement (S-007)
01/05/98 - 20-592 - FDA confirmed S-006 (bipolar)
Redacted
01/08/98 - 28,705 - Telephone conversation between Al Webber and Proj. Mgr. Steve Hardeman
01/09/98 - 20-592 - CSO Anna-Marie Weikel called with stat request
01/20/98 - 20-592 - Learned that S-006 was accepted for filing
01/27/98 - 28,705 - Submitted response to Dr. Andreason's 12/2/97 request
01/28/98 - 20-592 - Fax to Anna-Marie Weikel re stat request
01/28/98 - PADER
02/02/98 - 20-592 - Confirmed four-month safety update needed for S-006
02/02/98 - 28,705 - Call from Drs. Andreason and Laughren re: ECG data. Fax sent and document Fed Ex'd
02/04/98 - 20-592 - Al Webber and Charles Beasley talked to Drs. Laughren and Burkhart.
02/05/98 - 28,705 - Cross-reference letter for Dr. Wagner
02/05/98 - 28,705 - Steve Hardeman called regarding Zydis formulation pre-NDA meeting
02/05/98 - 20-592 - Diskette containing SAS info for Bipolar Mania sent to FDA
02/10/98 - 28,705 - HGGF amendment clarified with cover letter
02/11/98 - 28,705 - Cross-reference letter for Dr. Passick
02/13/98 - 28,705 - CIB submitted
02/20/98 - 28,705 - Submitted HGGI(a) (first version of protocol): relapse prevention
02/23/98 - 20-592 - Response to 2/4 request by Drs. Burkhart and Laughren
Redacted

02/26/98 - 28,705 – NTF re: Pre-NDA meeting teleconference for Zydis formulation
02/27/98 - 28,705 - Al Webber called FDA regarding Zydis formulation submission
03/04/98 - 55,342 - Submitted initial IND
03/05/98 - 28,705 - Cross-reference letter for Dr. Ron
03/05/98 - 55,342 - Sent desk copies of IND items 1-6 to Steve Hardeman
03/18/98 - 55,342 - Dr. Andreason requested further pK perspective. This was accomplished on 3/23
03/23/98 - 20-592 - S-007 approved
03/23/98 - 20-592 - FDA letter to Gerry Kirshner re: 12/19/7 CM&C supplement
03/25/98 - 28,705 - Submitted HGFI(a) (first version of protocol)
03/25/98 - 28,705 - Gary Tollefson letter to Tom Laughren regarding multiple issues
03/27/98 - 28,705 - Letter to FDA regarding adverse events in exempt health econ. studies
03/31/98 - 28,705 - Submitted request for feedback on depot polymer
03/31/98 - 20-592 - Submitted further support (manuscript) for 2/27/97 draft labeling
03/31/98 - 28,705 - Request for meeting on 11 topics and briefing document
04/01/98 - 55,342 - Proj. Mgr. Steve Hardeman called to say we may proceed
04/01/98 - 20-592 - Submitted four-month safety update
04/02/98 - 28,705 - Cross-reference letter for Dr. Bojrak
04/03/98 - 55,342 - Request for pre-NDA Meeting
04/06/98 - 20-592 - Seven-day alert call: US980401337
04/06/98 - 20-592 - Robert Young called to request names and addresses of bipolar mania investigators
04/08/98 - 20-592 - Submitted further ECG analysis info. [Note: UPS lost this submission. It was resubmitted with same date two weeks later]
04/10/98 - 20-592 - Sent info requested by Mr. Young on 7/6
04/17/98 - 20-592 - Dr. Hearst called with request for electronic assistance
04/20/98 - 28,705 - (should have been 20-592) Note to File: Dr. Hearst called with electronic request
04/22/98 - 55,342 - Submitted briefing document and confirmation for 5/14 meeting
04/24/98 - 28,705 - Letter to FDA confirming May 12 meeting
04/30/98 - 20-592 - Diskettes sent to Dr. Hearst
04/30/98 - PADER
05/08/98 - 28,705 - Cross-reference letter for Dr. Green
05/12/98 - 28,705 - Meeting with Neurpharm Div on several issues
05/12/98 - 28,705 – Lilly minutes on 05/12/98 meeting
05/14/98 - 55,342 - Pre-NDA meeting on SAIM
05/14/98 - 55,342 - Lilly minutes on 05/14/98 SAIM meeting
05/14/98 - 55,342 – Minutes of 05/14/98 meeting
05/15/98 - 28,705 - Submitted additional Phase I EKG info
05/18/98 - 20-592 - MRO Earl Hearst asked for electronic support

05/27/98 - 20-592 - Summary of 05/27/98 and 05/29/98 discussions regarding bipolar mania between Dr. Hearst and Todd Sanger

05/27/98 - 20-592 - Al Webber inquired status of bipolar mania supplement from CSO Anna-Marie Weikel

06/11/98 - 55,342 - Submitted series of LOAV amendments

06/12/98 - 28,705 - Cross-reference letter for Dr. Phillips

06/15/98 - 28,705 - Submitted protocal HGGN

06/16/98 - 28,705 - FDA FAXed response to 3/31/98 depot question

06/19/98 - 28,705 - Cross-reference letter for Dr. Bustillo

06/23/98 - 28,705 – Submitted protocol HGGB

06/25/98 - 55,342 - FDA response to initial IND

06/25/98 - 28,705 - Cross-reference letter for Dr. Stewart

07/02/98 - 20-592 - MRO Earl Hearst called with bipolar mania questions

07/06/98 - 20-592 - Summary of Dr. Earl Hearst/Todd Sanger discussions begun 07/06/98

07/13/98 - Several - Call to CSO Steve Hardeman re: several issues

07/16/98 - 20-592 - Diskette regarding bipolar mania sent to Dr. Hearst

07/22/98 - 28,705 - Cross-reference letter for Dr. Wirshing

07/22/98 - 28,705 - Cross-reference letter for Dr. Buckley

07/28/98 - 20-592 - Todd Sanger FAXed Factor Analysis regarding bipolar mania to Dr. Hearst at his request

07/29/98 - PADER

07/30/98 - 20-592 - Dr. Mabjob called with bipolar mania statistical question

08/11/98 - 55,342 - ADME Rpt No. 69

08/18/98 - 28,705 - Request for review of Zydis Trade name options

08/21/98 - 20-592 - Call from new bipolar mania CSO, Doris Bates

08/26/98 - 20-592 - Geriatric Labeling Supplement (S-008)

09/01/98 - 20-592 - Bipolar Mania chronology FAXed to CSO Doris Bates (note: 02/5/98 entry missing from chronology)

09/02/98 - 20-592 - S-008 (08/20/98) received

09/10/98 - 28,705 - Cross-reference letter for Dr. Quintana (new location)

09/23/98 - 28,705 - FDA feedback on protocal HGGB

09/23/98 - 28,705 – Comments on protocol HGGB from FDA

09/25/98 - 20-592 (SLR-002) - T. D. Revision not approvable

09/28/98 - 28,705 - Submitted final (abbreviated) report for HGCV and HGDY

09/29/98 - 20-592 - FDA Project Manager Doris Bates informed Al Webber that review of bipolar mania supplement was complete

10/01/98 - 20-592 – Ms. Holley (FDA) called re: Orange Book

10/02/98 - 20,592 – Not approvable letter for S-006

Redacted

10/05/98 - 28,705 - Meeting request for co-admin. for TRD

10/05/98 - 28,705 – Request for TRD/combo meeting

10/06/98 - 28-705 - Submitted protocal HGHD

10/07/98 - 20-592 - Letter to FDA with intention of amend T. D. supplement

10/08/98 - 20-592 - Letter to FDA with intention to amend bipolar mania supplement

10/09/98 - 20-592 - Proj. Mgr. Steve Handlman and Al Webber agreed on meeting date for mania.
10/09/98 - 20-592 - Meeting request re: Bipolar mania not approvable letter
10/09/98 - 20,592 – Request for meeting on bipolar mania
10/13/98 - 20,502 – Safety labeling change for priapism (S-010)

Redacted

10/16/98 - 20,592 – NTF re: Gladys Holley question from 10/01/98
10/23/98 - 28,705 – Cross reference letter for Dr. Kaye
10/27/98 - 20,592 – Letter to FDA confirming 11/06/98 meeting
10/28/98 - 20,592 – PADER
11/02/98 - 28,705 – Submitted protocol HGHG
11/03/98 - 28,705 – Zydis name discussion
11/03/98 - 20,592 – Amendment to 10/28/98 PADER
11/04/98 - 28,705 – Submitted protocol HGHQ
11/04/98 - 55,342 – Response to 6/25/98 FDA Letter on study LOAV
11/05/98 - 28,705 – Submission of protocol HGHR(a)
11/06/98 - 20,592 – Meeting with FDA on bipolar mania

Redacted

11/10/98 - 55,342 – FAX of info for Breier/Laughren conference call
11/10/98 - 20,592 – NTF re: FAX to Leber/Laughren
11/12/98 - 55,342 – NTF for conference call with Dr. Laughren
11/13/98 - 20,592 – NTF re: call between Doris Bates and Al Webber
11/16/98 - 20,592 – Submission of Lilly minutes from 11/06/98 meeting
11/18/98 - 28,705 – CM&C submission
11/19/98 - 20,502 – NTF re: call on typo in PV2964AMP
11/24/98 - 28,705 – Zydis name discussion, i.e. 8/18/98 submission

Redacted

12/01/98 - 20,592 – NTF re: statistical information sent on Alzheimer's psychosis
12/03/98 - 20,592 – FDA mintues of 11/06/98 meeting
12/03/98 - 20,592 – FDA sent their minutes of 11/06/98 meeting
12/08/98 - 28,705 – Migraine discussion with CSO Steve Hardeman
12/10/98 - 20,592 – NTF re: call on bipolar mania with Dr. Laughren

Redacted

12/15/98 - 28,705 – Letter re: Dr. Nakra discontinuation
12/16/98 - 28,705 – Zydis user fee # call

Redacted

01/06/99 - 28,705 – Amendment to 1997 Annual Report
01/11/99 - 28,705 – Informed FDA of error in 1/7/99 submission
01/11/99 - 20,592 – NTF re: call on bipolar mania
01/11/99 - 20,592 – Letter from FDA approving S-010 (10/13 safety change)
01/13/99 - 28,705 & 20-592 – Submitted plan for early termination of HGGW
01/14/99 - 20,592 – NTF re: call on HGEH audit
01/15/99 - 55,342 – Submitted clinical development plan for SAIM
01/18/99 - 55,342 – Cover letter with HGHB (b) submission

01/22/99 - 20,592 – NTF re: FAX to Al Webber on HGEH audit

01/25/99 - 20,592 – NTF re: call between FDA Project Manager Doris Bates and Al Webber on several bipolar mania issues

01/28/99 - 20,592 – FDA response to our 01/13/99 plan for HGGW (also FAX'ed)

02/05/99 - 20,592 – Letter responding to 01/28/99 communication on HGGW

02/08/99 - 20,592 – NTF re: call accepting p=<.05 for HGGW

02/10/99 - 55,342 – Amendment to SN-009 (01/15/99) submission

02/17/99 - 28,705 – Amendment to 1998 Annual Report

02/19/99 - 28,705 – Cross-reference letter for Kr. Krakowski

03/05/99 - 20,592 – Letter to FDA re: guidance on electr. Item 11 for bipolar mania

03/05/99 - 20-592 – Submission related to electronic format of Item 11

03/08/99 - 28,705 – Cross reference letter for Dr. Meltzer

03/08/99 - 20-592 – Sent confirmation of audit plan for HGEH

03/08/99 - 28,705 – Cross-reference letter for Dr. Meltzer

03/09/99 - 20-592 – Voice message from Doris Bates re: electronic Item 11

03/16/99 - 55,342 – Request for CM&C Pre-NDA meeting

03/16/99 - 28,705 – Submitted CIB

Redacted

03/17/99 - 21-086 – Correction of 2 errors in original NDA

Redacted

03/31/99 - 21-086 – NTF dates 3/31 re: CM&C question (3/23, 3/29, 3/30)

03/31/99 - 21-086 – CM&C Amendment

04/02/99 - 20-592 – FDA request for data (deaths, suicides)

Redacted

04/07/99 - 55,342 – Submitted protocol HGHW

04/12/99 - 20-592 – Bipolar mania amendment submitted (S-006)

04/13/99 - 28,705 – Type A meeting request for combo for TRD

04/16/99 - 20-592 – Doris Bates requested additional volumes from 4/12 mania amendment

04/16/99 - 21-086 – Dr. Zhoe (Biopharmaceutics Reviewer) called Greg Brophy (NTF)

04/20/99 - 28,705 – FAX of HGGI info (4/20 submission) to Dr. Laughren (blinded data)

04/20/99 - 28,705 – Submitted blinded summary of HGGI

04/20/99 - 21-086 – Voice mail to Dr. Zhoe regarding confirming date of Friday, 4/23 for telephone meeting

04/20/99 - 28,705 – Re: Ph4 Commitment – summary of I.A. of HGGI (FAXed to Dr. Laughren same day)

04/21/99 - 21,086 – Dr Zhoe called. Cannot have telephone meeting on 04/23/99. Suggests Friday, 04/30 or the following week (NTF)

04/22/99 - 20-592 – Sent diskette containing draft labeling sent to FDA Project

Manager Doris Bates

04/22/99 - 20-592 – FDA Project Manager Doris Bates called with 3 requests re: 4/12 amendment

04/23/99 - 20-592 & 28,705 – Conference call with Dr. Laughren re: mania, depot

04/23/99 - 21,086 – Called Dr. Zhoe to setup telephone meeting. She agreed to hold meeting 2:00 FDA time (1:00 our time) on Monday 05/03/99

04/23/29 - 28,705 – FAX to Dr. Laughren of 06/13/97 submission and p. 35 & 36 from protocol HGGI, sub. 02/20/98

04/26/99 - 55,342 – Submitted protocol HGHV

04/27/99 - 20-592 – Sent diskette containing HGGW 4/12 amendment to Doris Bates for Dr. Hearst

Redacted

04/28/99 - 28,705 – FAX from FDA re: stat question on HGGI I.A.

04/29/99 - 58,225 – Submitted new IND for orally disintegrating tablets

Redacted

04/29/99 - 20-592 – FAX of 2-page background on HGEH for conference call with Dr. Laughren

04/29/99 - 28,705 – Submitted response to stat question re: HGGI I.A.

05/03/99 - 20-592 – Melina Malandrucco retrieved my telephone call of 4/28 and left a voice mail – NTF

05/04/99 - 20-592 – Submitted audit for HGEH patients

05/04/99 - 55,342 – Submitted final study report LOAC

05/05/99 - 21,086 – Submitted to FDA responses to Zydis Biopharm questions

05/05/99 - 58,225 – FDA acknowledgement of IND

05/07/99 - 28,705 – Submitted protocol HGHL

05/10/99 - 55,342 – Confirmation of CM&C pre-NDA meeting/briefing document

05/11/99 - 20-592 – Call from Doris Bates to Al Webber regarding acute mania

05/11/99 - 28,705 – FAX of HGGI DMA minutes to Steve Hardeman

05/11/99 - 20-592 – FAX to FDA in response to stat reviewer request

05/12/99 - 28,705 – Cross reference letter for Dr. McElroy

05/19/99 - 28,705 – FDA concurrence with termination of HGGI

05/20/99 - 55,342 - SAIM CM&C pre-NDA meeting held.

05/27/99 - 55,342 - Submitted Lilly's minutes of 5-20 CM&C pre-NDA meeting.

05/27/99 - 20,592 – Response to 04/02/99 FDA letter

05/28/99 - 58,225 – Call from FDA: "may proceed"

Redacted

06/04/99 - 20-592 – Telephone discussion with Steve Hardeman on depot meeting (NTF)

06/11/99 - 20-592 – Submitted proposed pediatric study request

06/17/99 - 28,705 – Telephone discussion with Lana Chen regarding migraine (NTF)

06/22/99 - 20-592 – Depot meeting request

06/24/99 - 20-592 – Sent Dr. Hearst requested diskette (NTF)

06/30/99 - 58,551 – Initial IND submission

06/30/99 - 28,705 – Submitted protocol HGCY

07/01/99 - 58,551 – Voice mail to Melina Malandrucco informing her of IND submission

Redacted

07/02/99 - 55,342 – Change in pagination format notice

07/09/99 - 58,551 – Voice mail to Melina Malandrucco requesting IND number

07/09/99 - 51,457 – Change in pagination format notice

07/12/99 - 21-086 – Voice mail to Dr. Zhoe to confirm no questions on May 5th submission

07/13/99 - 20-592 – Voice mail to Steve Hardeman requesting response to 6/22/99 depot meeting request

07/13/99 - 28,705 – Cross reference for Dr. Hamilton

07/19/99 - 58,551 – Received FDA's written acknowledgement of IND receipt (dated 07/06/99)

07/19/99 - 20-592 – NTF re: conf. call on Adv. Com't mtg with Dr. Laughren

07/19/99 - 20-592 – Voice mail from Steve Hardeman offering August 17th for depot meeting

07/20/99 - 20-592 – Voice mail to Steve Hardeman confirming August 17th for depot meeting

07/21/99 - 20-592 – Steve Hardeman telephoned John Roth requesting switch of depot meeting to 8-26-99

07/22/99 - 20-592 – John Roth left voice mail to Steve Hardeman confirming 8-26-99 for depot meeting

Redacted

07/23/99 - 58,551 - VM from M. Malandrucco requesting NPI-X information and fax response

07/26/99 - 20-592 – Meeting request regarding Advisory Committee (faxed to Steve Hardeman)

Redacted

07/29/99 - 20-592 – Submitted PADER

07/29/99 - 20-592 – Submitted patent information

Redacted

07/29/99 - 58,551 – Call from Melina Malandrucco regarding initial IND (NTF)

Redacted

08/02/99 - 20-592 – NTF re: request for desk copy of Vol. 1 from 4/12 subm.

Redacted

08/05/99 - 20-592 – Written request for CMC depot meeting

08/05/99 - 28,705 – Informed FDA of discontinuation of Dr. Yoo
08/09/99 - 28,705 – Protocol addendum to HGGF
08/10/99 - 28,705 – Protocol amendment to HGGB
08/11/99 - 20-592 – Steve Hardeman left voice mail requesting e-mail of current PI; e-mail was sent

Redacted

08/20/99 - 28,705 - FDA request for revision of HGHL
08/23/99 - 20-592 (S009) - Fax to M. Malandrucco for August 25th teleconference between A. Breier, G. Brophy , and G. Tollefson (Lilly) and R. Katz and T. Laughren (FDA)
08/24/99 - 58,551 – FDA response to initial IND
08/25/99 - 28,705 – Received FDA request regarding Protocol HGHL (dated 08/20/99)
08/25/99 - 20-592 (S009) - Teleconference between A. Breier, G. Brophy , and G. Tollefson (Lilly) and R. Katz and T. Laughren (FDA)
08/26/99 - 20-592 – Meeting on depot

Redacted

09/01/99 - 28,705 - Submitted cross-ref. letter for Dr. Negron
09/02/99 - 20-592 – Submitted confirmation for 9/14 depot mtg
09/02/99 - 55,342 – Submitted request for SAIM plan confirmation
09/07/99 - 51,457 – Submitted meeting minutes of Aug 5th teleconference
09/08/99 - Submitted export authorization for olanzapine depot
09/10/99 - 58,225 – FDA response to IND submission
09/10/99 - 28,705 – Submitted response to FDA request on HGHL
09/10/99 - 28,705 & 58,551 – Submitted revised CIB (x-ref. to 51,457, 55,342, 58,551)
09/13/99 - 20-592 – Letter from FDA requesting safety changes
09/13/99 - 28,705 - Letter to FDA re: closing of HGHG
09/14/99 - 20-592 – CMC meeting on depot
09/15/99 - 20-592 – NTF re: Mania
09/20/99 - 58,551 – Submitted response to FDA response to initial IND
09/20/99 - 28,705 – Submitted delayed HGGI amendment (b)
09/22/99 - 20-592 – Submitted minutes from August 26 depot meeting
09/23/99 - 20-592 – NTF re: Mania
09/24/99 - 28,705 - Letter to FDA discontinuing Mexican site for HGHD
09/28/99 - 28,705 - Request for teleconference (Phase 4 Commitment)
09/29/99 - FDA authorization for shipment of depot formulation to Croatia
10/01/99 - 20-592 – NTF re: Mania
10/04/99 - 28,705 – Added nizatidine capsules

Redacted

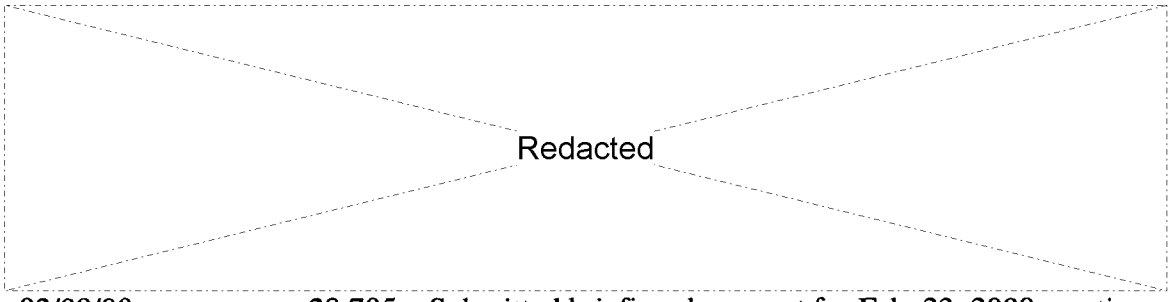
10/21/99 - 20-592 – FDA acknowledged our withdrawal of S-009

10/22/99 -	28,705 – HGHL protocol amendment in response to FDA 8/20/99 request
10/28/99 -	20-592 – Approvable letter for S-006 (bipolar mania)
10/29/99 -	20-592 – Advised FDA of our intent to amend S-006
11/03/99 -	28,705 – Cross-reference letter for Dr. Rudnik
11/04/99 -	28,705 – Cross-reference letter for Dr. Sikjah
11/8/99 -	28,705 & 21-086 – NTF re: telephone discussion between Al Webber and Michele Sharp (Lilly) and Steve Hardeman (FDA)
11/09/99 -	55,342 – Request for SAIM pre-NDA meeting
	Redacted
11/19/99 -	28,705 – Request for feedback on relapse prevention submission
11/23/99 -	20-592 – Submitted Study HGEU Safety Analysis
11/29/99 -	20-592 – Letter from FDA requesting submission of all adverse hematological events as 15-day Alert Reports
12/01/99 -	21-086 – NTF re: telephone discussion between Ann Maloney and CMC Reviewer Melissa Maust (FDA)
12/02/99 -	21-086 – NTF re: shipment of orally disintegrating tablet samples to CMC Reviewer Melissa Maust (FDA)
12/07/99 -	21-086 – Submission of proposed carton and container labels to FDA
12/07/99 -	20-592 – Response to FDA request 9/13/99 re: safety changes
12/10/99 -	20-592 – NTF re: telephone discussion between Al Webber and Project Manager Steve Hardeman (FDA)
12/13/99 -	55,342 - Submit SAIM pre-NDA briefing document and VM informing S. Hardeman of submission
12/14/99 -	28,705 – Cross-reference letter for Dr. Maguire
	Redacted
12/15/99 -	20-592 – Relapse prevention/maintenance of response submitted (S-011)
12/16/99 -	20-592 (S006) - NTF re: discussion between Gary Tollefson and Tom Laughren regarding bipolar mania labeling
12/17/99 -	20-592 – Advised FDA of our intent to comply with 11/29/99 request
12/17/99 -	28,705 – Cross-reference letter for Dr. Penzak
12/21/99 -	20-592 – FDA acknowledgement of relapse prevention supplement (S011)
12/22/99 -	20-592 (S006) – Submitted response to S-006 (bipolar mania) approvable letter; VM to D. Bates informing of submission
12/23/99 -	20-292 (S006) - VM from D. Bates confirming receipt
12/23/99 -	21-086 – Approvable letter for orally disintegrating tablet
12/23/99 -	28,705 – Submitted safety data from Study HGEU as requested by FDA in bipolar mania approvable letter (10/28/99)
12/23/99 -	28,705 – Submitted additional safety analysis from Study HGEU as requested by Dr. Laughren to Dr. Tollefson on 12/16/99

12/23/99 -	20-592 – Submitted 6 desk copies of response to bipolar mania approvable letter
12/30/99 -	20-592 (S006) - NTF re: VM from D. Bates and subsequent telephone discussion
01/04/00 -	21-086 – Advise FDA on our intent to amend
01/04/00 -	55,342 - NTF re: telephone discussion with S. Hardeman on 01/06/00 SAIM pre-NDA meeting
01/06/00 -	20-592 (S006) - FDA acknowledgement of receipt of Lilly's 12-22 full response to approvable letter
	Redacted
01/11/00 -	28,705 – Cross-reference letter for Dr. Kaplan
01/12&14/00 -	20-592 (S006) - NTF re: telephone discussions w/ Doris Bates on full response to October 28, 1999 approvable letter
	Redacted
01/17/00 -	28,705 - Submitted Protocol HGIM
01/18/00 -	20-592 (S006) - Telephone discussion between G. Brophy and R. Katz on timing of FDA's review of Lilly's full response to approvable letter
	Redacted
01/20/00 -	20-592 (S006) - VM to Doris Bates requesting that she follow-up G. Brophy's teleconference with Dr. Katz on option of deferring Feb Lilly meetings to speed review of bipolar mania response
	Redacted
01/21/00 -	55,342 - Submitted Lilly's meeting minutes for January 6th pre-NDA meeting
01/21/00 -	20-592 (S006) - VM from Doris Bates stating she checked with Dr. Katz and deferring Feb Lilly meetings would not help speed bipolar mania response review.
01/24/00 -	20-592 (S011) – NTF VM from Steve requesting desk copies
01/24/00 -	55,342 - NTF re: telephone discussion with Dr. Vijay Tammara (Biopharm Reviewer, FDA) regarding financial disclosure
	Redacted
01/27/00 -	21-086 – Submitted complete response to approvable letter (12/23/99)
01/31/00-	28,705 – NTF re: telephone discussions with Mr. Steve Hardeman about scheduling bipolar clinical plan meeting
01/31/00 -	20-592 – NTF re: desk copies of S011 (Relapse Prevention)
02/04/00 -	55,342 - NTF re: pre-NDA meeting follow-up discussion between Stacey David and Dr. Kun Jin (FDA)
02/04/00 -	21-086 – NTF re: telephone discussion with Mr. Steve Hardeman about faxing label revision

02/04/00 - 20-592 – NTF re: telephone discussion with Mr. Steve Hardeman concerning FDA agreement with our recommendations in December 7, 1999 submission

02/04/00 - 20-592 (S006) - VM from Doris Bates - no new information on bipolar mania status, submitting Pediatric Plan and Proposed Pediatric Study Request in one submission is preferred to two separate submissions



02/09/00 - 28,705 – Submitted briefing document for Feb. 23, 2000 meeting with FDA regarding bipolar clinical plan

02/11/00 - VM to Sandra Titus informing her of our intentions to submit written statement and make oral presentation at March 9th Advisory Committee meeting

02/11/00 - 20-592 (S006) - Telephone call from Doris Bates - Doris informed me she expected fax of FDA's counterproposal for bipolar mania labeling to be mid-next week; I confirmed our plans to request deferral for submitting PPSR for Bipolar Mania until after we received response on Psychosis PPSR

02/15/00 - 20-592 (S006) - FDA counterproposal on bipolar mania labeling received by fax

02/16/00 - 20-592 (S006) - Responded to page from Doris Bates - set up 10:30 AM teleconference for February 22nd for final agreement on bipolar mania labeling

02/16/00 - Submitted Lilly written statement for March 9th Advisory Committee meeting

02/16/00 - 21-086 – NTF re: status of FDA review of response to approvable letter

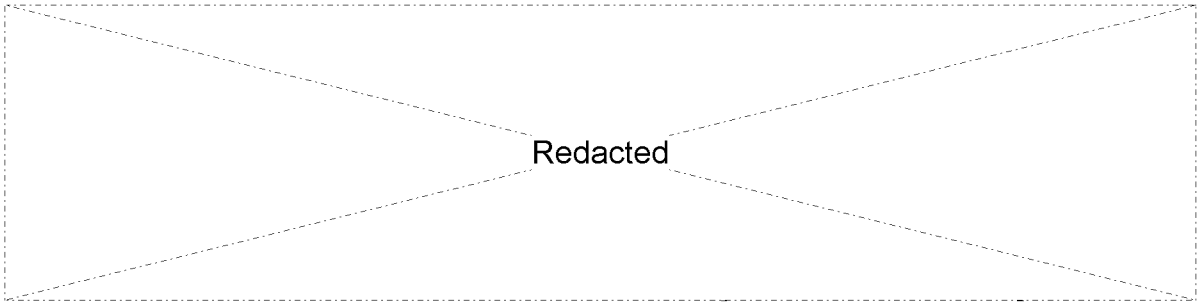
02/17/00 - Responded to page from Sandra Titus; informed her of Alan Breier's presentation at March 9th Advisory Committee meeting; she requested outline of presentation one week prior (could be written statement)

02/18/00 - 20-592 (S006) - Sent fax supporting February 22nd bipolar mania labeling teleconference; confirmed FDA receipt with telephone call to Doris Bates

Redacted

02/22/00 - 20-592 (S006) - NTF re: FDA Teleconference on Bipolar Mania labeling

02/23/00 - 55,342 - NTF re: telephone discussion with Steve Hardeman on SAIM PK studies

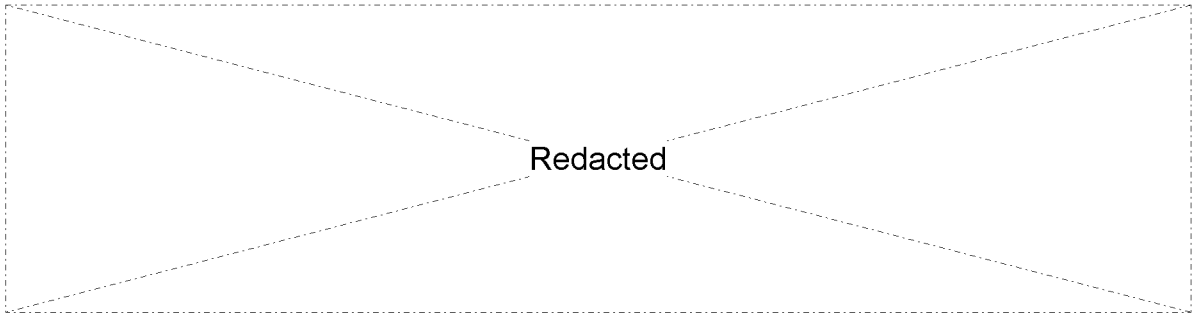


02/25/00 -	20-592 (S006) - Received fax of FDA's bipolar mania labeling incorporating agreements from label discussions held 2-22 and 2-23
02/25/00 -	20-592 (S006) - In response to Doris Bates' telephone request, faxed copy of cover letter for bipolar mania pediatric plan to confirm our intent to submit today (ie, 120 days after approvable letter)
02/25/00 -	20-592 (S006) - Submitted Phase 4 commitment bipolar mania pediatric plan
02/25/00	55,342 - Submitted toxicology exposure table requested by FDA at SAIM pre-NDA meeting to justify not doing an SAIM rat toxicology study
02/28/00 -	20-592 (S006) - NTF re: Doris Bates telephone call to request confirmation on currently approved label version
02/28/00 -	20-592 (S006) - Faxed Lilly agreement with FDA's 2-25-00 faxed label proposal and confirmed PV3330AMP as currently approved label
02/28/00 -	20-592 (S006) - NTF re: Doris Bates telephoned to suggest superceding geriatric supplement (S008); Division willing to accept proposed text in *Geriatric Use* subsection of S006 proposed labeling
02/28/00 -	28,705 – Cross-reference letter for Dr. Sikich
02/28/00 -	20-592 (S011) – Received fax from FDA requesting SAS datasets for Study HGGI
02/29/00 -	20-592 (S006) - Faxed to Doris Bates Lilly's agreement with 2-28 fax version of labeling from FDA and Lilly's agreement with FDA's proposal to supercede S008 with S006 for *Geriatric Use* subsection
03/03/00 -	20-592 (S006) - NTF re: Doris Bates request for Zyprexa labeling history from PV2963AMP and fax response to Doris' request
03/06/00 -	55,342 - submitted HGIO and HGJA Protocol Summaries for FDA feedback
03/06/00 -	Telephoned FDA for NDA number for SAIM olanzapine NDA; the number is 21-253.
03/06/00 -	20-592 (S006) - Received fax from Doris Bates with minor labeling edits (ie, underlines for changes from PV3330AMP; no text changes)
03/07/00 -	20-592 (S006) - Faxed back response to Doris' 03/06/00 fax

03/07/00 -	55,342 - NTF re: Telephone discussion with Steve Hardeman on protocol summaries for HGIO and HGJA; pre-meeting for March 16th meeting scheduled for AM on the 15th; faxed HGIO and HGJA protocol summaries to Steve
03/08/00 -	55,342 - Telephone call to Steve Hardeman re: Rich Bergstrom's plan to call Dr. Chandra Sahajwalla (Supervisory Biopharmaceutics Reviewer)
03/08/00 -	Sent Powerpoint slides to Sandra Titus for Alan Breier's presentation for the March 9th PDAC meeting
	Redacted
03/13/00 -	55,342 - NTF re: Rich Bergstrom's discussion with Dr. Chandrahas Sahajwalla (Acting Deputy Director - Division of Biopharmaceutics)
03/15/00 -	21-086 – Voice mail from Steve Hardeman re: Zydis review status
03/15/00 -	20-592 (S011) – NTF re: Request for desk copies from Dr. Constance Lewin (Medical Reviewer) regarding data from 2 sites in Study HGGI
03/16/00 -	20-592 (S011) – NTF re: Phone discussion with Dr. Lewin
03/16/00 -	28,705 – Meeting minutes from Feb. 23 meeting re: Bipolar Clinical Plan submitted.
	Redacted
03/17/00 -	20-592 (S006) - APPROVAL FOR BIPOLAR MANIA. Telephone call from Doris Bates (10 AM) informing us she was faxing approval letter. Called her back at 11:30 to confirm fax receipt and acceptability of accompanying labeling.
03/21/00 -	21-086 – Telephone call from Steve Hardeman re: request for Zydis label using bipolar mania approved label.
03/20/00 -	55,342 - Submitted pre-NDA meeting follow-up regarding statistical plan
03/22/00 -	20-592 (S006) - submitted bipolar mania launch promotional materials to DDMAC and the Neuropharm Division
03/22/00 -	28,705 – Cross-reference letter for Dr. Biederman
03/23/00 -	20-592 (S011) – NTF re: E-mail from Steve requesting datasets for Study HGGI
03/24/00 -	55,342 - E-mail from Steve Hardeman stating Biopharm's (Drs. R. Baweja and Vanitha Sekar) request for teleconference to discuss HGIO and HGJA
03/24/00 -	55,342 - NTF re: telephone discussion with Steve Hardeman to set up 1:30 teleconference on 3-27-00 to discuss PK protocols HGIO and HGJA
03/27/00 -	Export authorization request for shipment to Brazil
03/28/00 -	20-592 (S011) – Telephone call from Dr. Paul Andreason re: request for additional analyses from Study HGGI

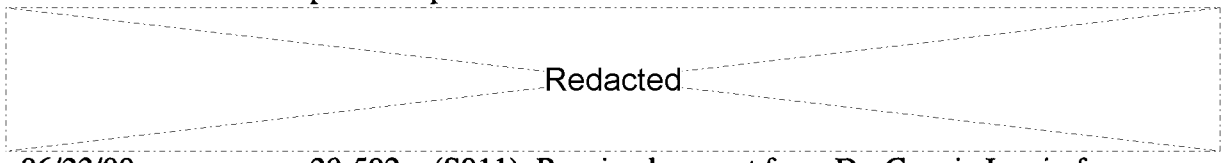
03/28/00 -	20-592 (S011) – Dr. Susan Hamilton (Lilly) talked with Dr. Siddiqui (FDA statistician) regarding the request for datasets for Study HGGI
04/05/00 -	55,342 - NTF re: receipt of Steve Hardeman e-mail with Biopharmaceutics comments responding to Serial No. 036
04/05/00 -	55,342 - NTF re: telephone discussion with Steve Hardeman on Biopharm's e-mail comments
04/07/00 -	21-086 – Received by fax approval letter (dated 04-06-00)
04/07/00 -	21-086 – NTF re: telephone discussion with Steve Hardeman to clarify approval letter content
04/11/00 -	20-592 – NTF re: telephone discussion with Steve Hardeman to discuss registration strategy of 1 mg tablet
04/11/00 -	55,342 - Greg Brophy discussed Biopharm's 4/5/00 e-mail comments with Drs. Katz and Laughren following PMDD meeting at FDA; Drs. Katz and Laughren agree with Lilly's position stated in 04/13/00 letter
04/12/00 -	28,705 – Cross-reference letter for Dr. Mathis
04/13/00 -	55,342 - Submitted written response to 4/5/00 e-mail comments from Biopharm
04/14/00 -	Faxed and submitted hard copy depot export authorization amendment for HGIL in Croatia to Michelle Limoli; followed-up with voice mail notification of fax and hard copy submission
04/16/00 -	55,342 - E-mail notification to Steve Hardeman of 04/13/00 submission
04/17/00 -	28,705 – Cross-reference letter for Dr. Brown
04/21/00 -	55,342 and 28,705 - VM to Steve Hardeman regarding status of Pharm/Tox review of SAIM exposure table and combo proposed tox doses and Biopharm review of our 4-13 written response
04/24/00 -	28,705 – Letter to FDA discontinuing Dr. Reddy's site for HGHL
04/24/00 -	20-592 (S-006) - NTF re: discussion with Doris Bates on our response to March 17th approval letter
04/25/00 -	55,342 - NTF re: telephone discussion with Steve Hardeman regarding status of pharm/tox review of SAIM exposure table, combo proposed doses and Biopharm review of 4-13 written response.
04/26/00 -	20-592 (S-006) - Submitted bipolar mania FPL
05/01/00 -	28,705 – Cross-reference letter for Dr. Taylor
05/02/00 -	55,342 - E-mail to Steve Hardeman requesting status of Dr. Baweja's review of Lilly April 13th written response
05/05/00 -	21-086 – Zydis FPL (package insert only) submitted
05/09/00 -	20-592 – 314.70(c) label change submitted for hyperglycemia
05/10/00 -	20-592 – Received FDA letter dated May 1, 2000 requesting hyperglycemia data
05/10/00 -	55,342 - Received e-mail from Steve Hardeman (forwarded from Dr. V. Sekar - Biopharm Reviewer) requesting confirmation of our

	intentions to market (a) SAIM vials alone, (b) SAIM Kit, or (c) both. E-mailed confirmation of our intention to market both.
05/15/00 -	Received faxed FDA letter dated May 12, 2000 granting export authorization of olanzapine to Brazil for global IIT study conducted by Dr. Marcia Rozenthal
05/17/00 -	21-086 – Zydis FPL (5 mg and 10 mg immediate container labels and cartons only) submitted
05/17/00 -	55,342 - NTF re: telephone discussion with Steve Hardeman on submission of study reports for HGIO and HGJA
05/17/00 -	20-592 - FDA letter acknowledging receipt of S012 (received at Lilly 05/24/00)
05/17/00 -	E-mail to Steve regarding Zydis FPL submission, alert him to telephone discussion between Dr. Beasley and Dr. Laughren regarding hyperglycemia, and asked for status of S011 submission.
05/19/00 -	55,342 - NTF re: e-mail from Steve Hardeman confirming the acceptability of submitting the HGIO study report within 4-months of the initial NDA submission.
05/22/00 -	21-086 – Request for waiver of PADER requirement
05/24/00 -	20-592 – Received acknowledgement dated 05/17/00 of labeling supplement (hyperglycemia) submitted on 05/09/00 given supplement number 012
	Redacted
06/01/00 -	21-253 - NTF re: telephone discussion with Steve Hardeman (NDA submission plans, potential for priority review, FDA feedback on pharm/tox exposure table, schizophrenia pediatric status, planned depot IND submission)
06/05/00 -	20-592 (S006)- Submission of "Dear Healthcare Practitioner" letter in response to March 17, 2000 bipolar mania approval letter
06/07/00 -	55,342 – Submitted HGJA amendment (a)
06/07/00 -	20-592 - NTF re: LeeAnn Chambers discussion w/ Dr. Robert Seevers (FDA) on depot stability proposal
	Redacted
06/12/00 -	21-253 - Submitted user fee check to Mellon Bank
	Redacted
06/14/00 -	20-592 (S006) - NTF re: Doris Bates request for a WORD version of bipolar mania FPL
06/15/00 -	21-253 - Original submission of Zyprexa IM NDA; informed Steve Hardeman of submission by e-mail
	Redacted



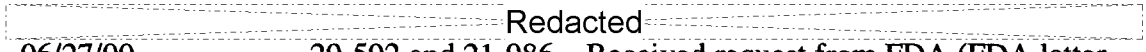
06/20/00 - 28,705 - Submitted Protocol HGIY

06/20/00 - 21-253 - NTF re: telephone requests from Doris Bates for desk copies of selected volumes of original submission / discussion of pediatric plan



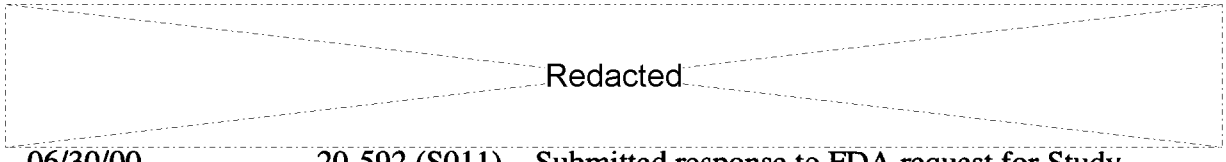
06/22/00 - 20-592 – (S011) Received request from Dr. Connie Lewin for Study HGGI data for audit of investigator sites in Croatia

06/23/00 - 28,705 - Submitted olanzapine CIB (cross-reference letters submitted to 55,342, 58,551,58,225, and 51,457)



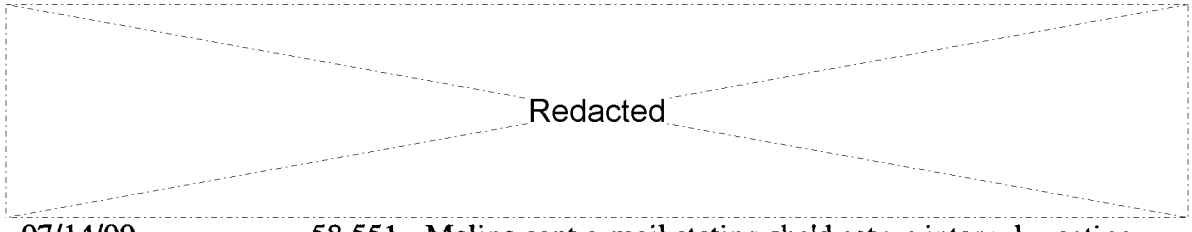
06/27/00 - 20-592 and 21-086 – Received request from FDA (FDA letter dated June 16, 2000) to supply person-time exposure data, datasets and death narratives from clinical trial database

06/27/00 - 51,457 - NTF re: telephone call from Dr. Paul Andreason responding to Serial No 047 (submitted 6-13-00) request for feedback on HGGU amendment and recommending submission of amendment

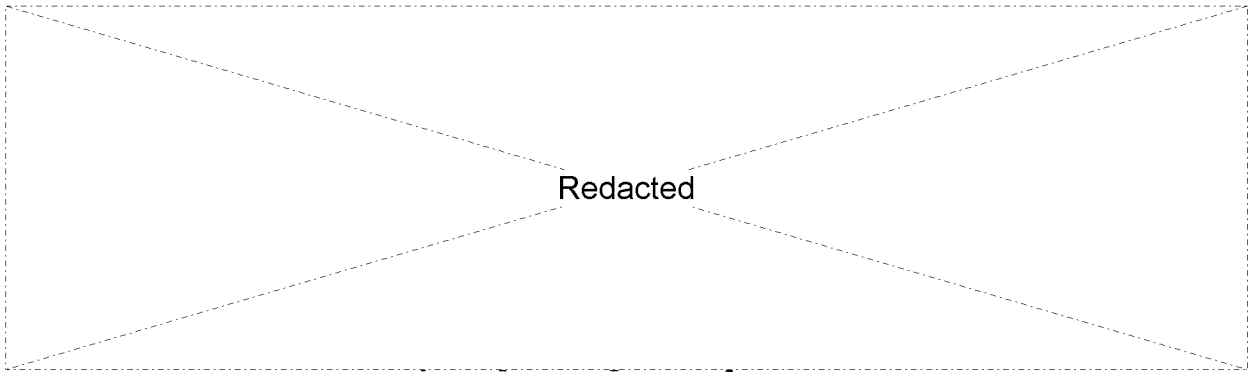


06/30/00 - 20-592 (S011) – Submitted response to FDA request for Study HGGI data for Croatia audit

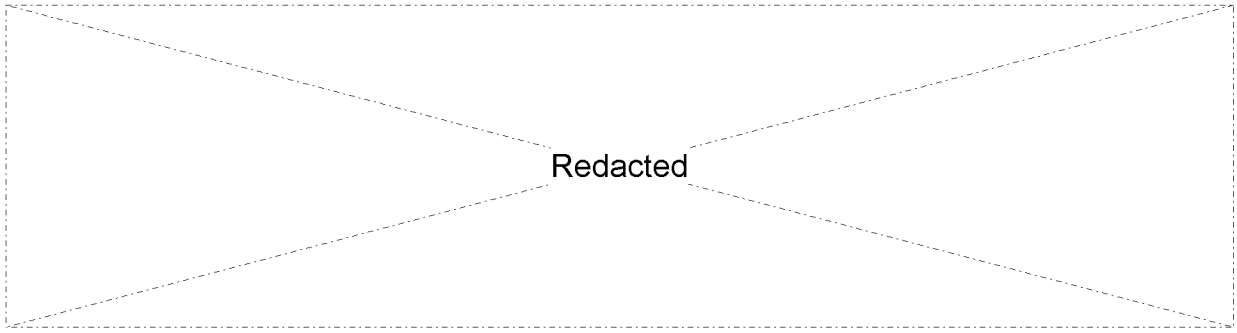
07/11/00 - 21-086 - Received letter dated July 5, 2000 from FDA agreeing to waive quarterly PADER requirements



07/14/00 - 58,551 - Melina sent e-mail stating she'd set up internal meeting for 07/26/00 at noon (EDT) to review the interim analysis plan and requesting that Lilly be available for teleconference in case of any questions.



07/25/00 - 28,705 - CMC Amendment submitted



07/28/00 - 28,705 – Cross-reference letter for Dr. Kim

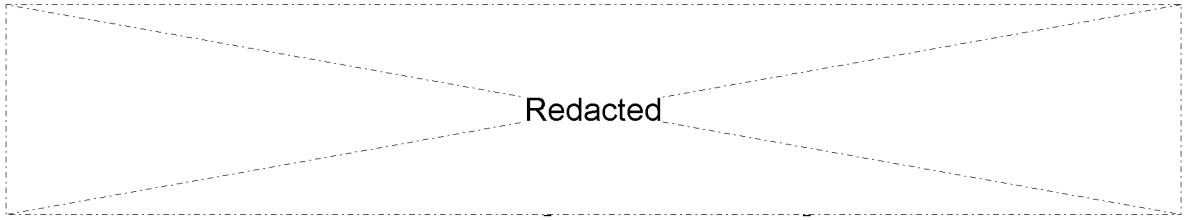
Redacted

07/31/00 - 20-592 – Submitted response to May 1, 2000 letter (hyperglycemia)

Redacted

08/02/00 - 21-253 - Telephone request from Dr. Constance Lewin, Division of Scientific Investigations, FDA, for information on four pivotal trials

08/07/00 - E-mail to S Hardeman giving heads-up on depot IND submission



08/08/00 - 60,701 - Initial IND submission for olanzapine pamoate monohydrate depot formulation

08/08/00 - 28,705 - Cross-reference letter for Dr. Kim

08/09/00 - 21-253 - Submitted pivotal trial information responding to Dr. Lewin's August 2nd telephone request

08/09/00 - 28,705 – Cross-reference letter for Dr. Pettinati

08/09/00 - 28,705 – Notification of discontinued investigator, Dr. Robert Mitchell

Redacted

08/10/00 - 21-253 - Submitted investigator information responding to Dr. Connie Lewin's August 2nd request

08/11/00 - Submitted export authorization request for export of olanzapine pamoate monohydrate depot CT material to Croatia for LOBE

08/14/00 - 28,705 - Submitted Addendums 5 & 6 for HGGF

08/16/00 - 60,701 - E-mail from Steve Hardeman requesting desk copies of initial IND submission and assigning IND number

08/16/00 - 60,701 - Acknowledgement letter from FDA

Redacted

08/17/00 - 60,701 - Sent desk copies to Steve Hardeman in response to 8/16 request

Redacted

08/24/00 - 20-592 (S006) - NTF re: e-mail to Doris Bates requesting status of Division's review of February 25, 2000 submission of Phase 4 pediatric study

08/24/00 - 21-253 - NTF re: telephone call from Dr. Connie Lewin (Division of Scientific Investigations, FDA) requesting information on Zyprexa IM sites for FDA audits

08/31/00 - 21-253 - Telephone discussion with Sandra Titus regarding status of February 2001 Advisory Committee meeting; she agreed to follow-up with T. Laughren/R. Katz for additional clarification

Redacted

09/05/00 - 20-592 - NTF re: e-mail communications w/ Doris Bates and Steve Hardeman regarding status of psychosis and bipolar mania pediatric proposals.

09/05/00 - 60,701 - NTF re: e-mail from Steve Hardeman stating that studies under IND 60,701 can proceed

Redacted

09/07/00 - 28,705 - Informed FDA of discontinuation of Dr. Menas as HGFI investigator

Redacted

09/07/00 - 21-253 - NTF re: e-mail communications w/ Sandra Titus following-up 08/31/00 telephone discussion inquiring if she had any information on date/format, etc.

Redacted

09/12/00 -	21-253 - NTF re: e-mail to Sandra Titus confirming our understanding of a February 2001 Advisory Committee meeting
09/12/00 -	21-253 - Submitted response to Dr. Constance Lewin's August 24, 2000 request for information for investigator site audits
09/14/00 -	60,701 - FDA letter responding to initial IND submission
09/14/00 -	20-592 (S006) - Submitted market package of Zyprexa in response to March 17, 2000 approval letter
	Redacted
09/14/00 -	20-592 (S011) – E-mailed re-analysis of benzodiazepine use section (double-blind maintenance phase) of HGGI report to Steve Hardeman
09/14/00 -	20-592(S006) - Submitted on market package of Zyprexa in response to request in March 17, 2000 approval letter
09/15/00 -	20-592 –314.70(c) labeling change with revision to Overdosage section
09/15/00 -	21-253 - NTF re: discussion with Steve Hardeman on SAIM Advisory Committee meeting, Biopharmaceutics meeting request for OFC, status of HGGU amendment, and status of pediatric
09/18/00 -	21-253 - Acknowledgement letter from FDA for June 15th initial NDA submission
	Redacted
09/20/00 -	21-253 - NTF re: request for telephone discussion between Drs. Laughren and Breier to discuss PDAC meeting
	Redacted
09/20/00 -	60,701 - Receipt of FDA letter dated 09/14/00 responding to initial IND submission
09/22/00 -	20-592 (S013) – FDA acknowledgement of labeling supplement submitted 9/15/00
09/22/00 -	21-086 (S001) - FDA acknowledgement of labeling supplement submitted 9/15/00
09/22/00 -	20-592 - Submitted meeting request for CM&C depot meeting
09/25/00 -	20-592 & 21-086 – FDA letter on class labeling for antipsychotics; treatment of schizophrenia
09/26/00 -	28,705 - Submitted Olanzapine CIB
09/27/00 -	28,705 - CM&C amendment submitted
09/29/00 -	21-253 - NTF re: telephone discussion w/ Steve Hardeman on Advisory Committee meeting
	Redacted

09/29/00 - 20-592 - Submitted Annual Report Amendment of updated stability data

10/02/00 - 21-086 – Submitted copy of May 9, 2000 labeling supplement originally submitted to 20-592

Redacted

10/04/00 - 21-253 - Telephone request from Dr. Seevers (FDA) to Toby Massa for additional CM&C information

10/5/00 - 21-086 – Approval letter for Zydis FPL submission (05/05/00)

10/10/00 - Export authorization request for SAIM CT material to Singapore

Redacted

10/11/00 - 28,705 – NTF FDA request from Dr. Lewin for protocol HGFI and investigator Dr. Mena

10/11/00 - 21-253 - Submitted 4-month safety update consisting of Study Reports HGIO and HGJA

10/12/00 - 20-592 (S011) – Approvable letter received by e-mail from Steve Hardeman

10/12/00 - 21-253 - NTF re: telephone discussion w/ Steve Hardeman

10/13/00 - 21-086 (S002) – Received acknowledgement of 314.70(c) labeling change submitted on 10/2/00 (copy of 5/9/00 labeling change)

10/13/00 - 28,705 - Response to request from Dr. Lewin for Protocol HGFI and investigator Dr. Mena

Redacted

10/16/00 - 20-592 (S011) – Submitted intent to file amendment to approvable letter

10/16/00 - 21-253 - Submitted CM&C amendment responding to Dr. Seevers' October 4th request

Redacted

10/18/00 - 20-592 - Submitted briefing document for October 24th CM&C depot meeting

10/18/00 - 20-592 (S011) – Submitted complete response to approvable letter (10/12/00)

10/20/00 - 20-592 (S012), 21-086 (S002) – Received letter dated 10/11/00 regarding 314.70(c) labeling change submitted 5/9/00

Redacted

10/24/00 - 21-253 - Submitted alternative tradenames/sent WORD copy of submission to Steve Hardeman on 10/25

10/24/00 - 20-592 (S011) – Approvable letter dated 10/12/00 received by mail

10/24/00 - 20-592 - CM&C depot meeting

Redacted

Redacted

11/01/00 - 21-253 - Re-sent e-mail to Steve Hardeman of October 24th alternative tradename proposal (in response to 10/31/00 telephone discussion)

11/01/00 - 21-253 - NTF re: e-mail communications w/ Sandra Titus establishing that PDAC is scheduled to meet February 14 & 15, 2001

11/02/00 - Export authorization approval letter received for shipment of SAIM CT material to Singapore for LOBI study

Redacted

11/2/00 - 28,705 – Submitted Protocol F1D-US-HGJB

11/3/00 - 21-253 - NTF re: telephone discussion w/ Steve Hardeman regarding HGHX amended study report/ISS update

Redacted

11/06/00 - 28,705 - Cross-reference letter Dr. Joseph Goldberg

11/07/00 - 20-592 - Submitted request for FDA written feedback on current IM olanzapine depot clinical plan

11/07/00 - 60,701 - Telephone discussion with Steve Hardeman regarding plans to amend Protocol LOBE to allow up to 300 mg injection

11/08/00 - 60,701 - NTF re: e-mail request to Steve Hardeman for Division's agreement to amend Protocol LOBE to allow up to 300 mg injections

11/09/00 - 21-253 - Received e-mail from Steve Hardeman indicating that the Advisory Committee meeting for Lilly will be February 14, 2001 and for Pfizer will be February 15, 2001

11/09/00 - 28,705 - E-mail to Steve Hardeman regarding possibility of adding Biopharmaceutics Reviewer for November 14th meeting

11/09/00 - 20-592 (S011) – Received approval letter by e-mail from Steve Hardeman

Redacted

11/14/00 - 21-253 - NTF re: discussion with Steve Hardeman on submission of amended HGHX report, ISS and updated draft labeling

11/17/00 - 60,701 - E-mail to Steve Hardeman following up 11/08/00 e-mail requesting Division's agreement to amend Protocol LOBE

11/17/00 - 21-253 - E-mail from Steve Hardeman stating that he discussed with Dr. Laughren our intention to meet with the Division before the February Advisory Committee meeting and Dr. Laughren indicated he would not want to meet before the latter part of January 2001

11/17/00 - 60,701 - E-mail to Steve Hardeman requesting status of review of planned LOBE amendment (e-mail sent 11/08) and response from Steve that Dr. Laughren also needs to review

11/17/00 - 21-253 - E-mail to Sandra Titus requesting the location (ie, hotel) of the February 2001 Advisory Committee meeting

Redacted

11/21/00 - 28,705 - Cross-reference letter for Drs. Loehrer and Passik

Redacted

11/28/00 - 20-592 (S011) - Received hard-copy of approval letter received by e-mail on 11/09/00

11/29/00 - 20-592, 21-086 - Submitted FPL

11/30/00 - 21-253 - Sent Steve Hardeman CD-ROM copies of amended HGHX clinical study report

11/30/00 - 21-253 - NTF re: telephone discussion with Sandra Titus re: February 14th PDAC

Redacted

12/01/00 - 21-253 - NTF re: e-mail from Steve Hardeman regarding OPDRA consult on proposed tradenames

12/01/00 - 60,701 - NTF re: e-mail of Dr. Andreason's request for pk data to support LOBE amendment proposal

12/01/00 - 21-253 - Submission of amended HGHX clinical study report

12/01/00 - 21-253 - E-mail to Steve Hardeman notifying him of the submission yesterday of the HGHX CD-ROMs and today of the paper copy

12/01/00 - 60,701 - E-mail to Steve Hardeman requesting status update on 11/08 request to amend Protocol LOBE

12/06/00 - 21-253 - NTF re: telephone discussion w/ Sandy Titus re: PDAC meeting logistics (audio-visual equipment, presentation slides)

12/07/00 - 21-253 - NTF re: e-mail exchange w/ Steve Hardeman regarding OPDRA's consult on ZYPREXA IntraMuscular tradename

12/08/00 - 21-253 - Submitted meeting request to discuss PDAC meeting; also sent WORD copy to Steve Hardeman by e-mail

12/08/00 - 28,705 - Submitted protocol F1D-MC-HGJN

12/10/00 - 21-253 - E-mail request to Steve Hardeman for agreement on submission of unannotated draft labeling (not annotated) with submission of updated ISS

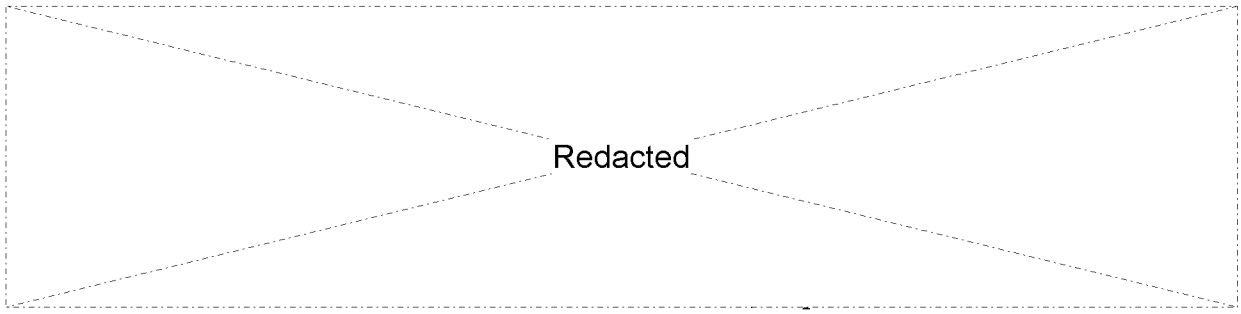
Redacted

12/15/00 - 21-253 – Received FDA CMC information request

12/18/00 - 28,705 - Submitted protocol F1D-MC-HGJJ

Redacted

12/20/00 - 21-253 - Submitted amended ISS and updated draft labeling



01/05/01 -	60,701 - E-mail request to Steve Hardeman for status of proposed LOBE amendment
01/05/01 -	21-253 - Submitted response to Steve Hardeman's 12/20/00 e-mail request to Lisa Carlson for Hyporet syringes
01/08/01 -	21-253 - Submitted response to 12/13/00 CMC questions
01/11/01 -	21-253 - Submitted confirmation and supporting information for 1/18/01 meeting
01/12/01 -	60,701 - Follow-up e-mail request to Steve Hardeman on status of Dr. Andreason's review of LOBE amendment
01/15/01 -	21-253 – Submitted supporting information for 01/18/01 meeting
01/16/01 -	21-253 – Submitted IM pediatric plan requested in FDA 09/18/00 letter
01/17/01 -	60,701 – E-mail from Steve Hardeman communicating acceptability of proposed LOBE amendment
01/19/01 -	21-253 - Received FDA Fax Request for oral olanzapine clinical trial data pertinent to bradycardia/hypotension
01/22/01 -	60,701 – Submitted Protocol Amendment LOBE(a)
01/24/01 -	20-592 – Submitted CMC meeting minutes for 9/14/99 and 11/8/00 CMC depot meetings
01/24/01 -	21-253 - NTF re: telephone discussion between Charles Beasley/John Roth and Greg Dubitsky on 1/19/01 FDA fax request
01/25/01 –	21-253 – FDA proposed redactions of FDA Advisory Committee background reviews
01/29/01 -	21-253 – Received FDA CMC Information request (letter dated 1/23/01)
02/01/01 -	21-253 – Submitted CMC response to FDA information request received on 01/29/01
02/01/01 -	21-253 - Submitted recommended redactions of PDAC briefing information to Sandra Titus; a fax copy was also sent to S Titus and R Castle
02/02/01 -	28,705 - Submitted CMC amendment for use of comparator amantadine
02/05/01 -	21-253 - NTF re: e-mail to Dr. Dubitsky re: case of "cardiac arrest" discussed during 1/18/01 FDA meeting
02/06/01 -	28,705 – Submitted protocol F1D-MC-S013
02/08/01 -	21-253 - Received letter from Roy Castle, FDA re: redactions of PDAC briefing document (letter dated 02/02/01)

02/09/01 - 28,705 – E-mail request to Steve Hardeman for status of Feb. 23, 2000 (bipolar clinical plan) Redacted depression clinical plan) meeting minutes

Redacted

02/23/01 - 20-592 – CM&C supplement submitted for Zyprexa tablets
02/23/01 - 21-253 - Issuance of 483 following PAI of Building 105-LTC
02/28/01 - 20-592 – E-mail to Hardeman requesting response to Nov 7, 2000 submission regarding depot clinical plan questions
03/02/01 - 21-253 – FDA Warning Letter resulting from PAI
03/05/01 - 20-592 (S014) - Received FDA acknowledgement of CBE-30 supplement, dated 2/27/01
03/05/01 - 21-253 - Received FDA CMC/microbiology questions, dated 2/27/01

Redacted

03/06/01 - 21-253 - Receipt by Lilly of Warning Letter, dated 3-2-01, for PAI of Building 105
03/07/01 - 21-253 - Submitted revised draft packaging labeling
03/08/01 - 21-253 - NTF re: telephone discussion with S Hardeman on PAI inspection/action letter
03/09/01 - 21-253 - Submitted response to 2/27/01 CMC/microbiology request (received 3/05/01)
03/09/01 - 21-253 - E-mail to Steve Hardeman of 483 (PAI Inspection) and Lilly response to 483 in response to his 3/8 telephone request
03/12/01 - 21-253 - Telephone discussion between T. Massa and R. Seevers (FDA) re: impact of PAI on CMC action letter recommendation
03/12/01 - 21-253 - Submitted 483 (PAI Inspection) and Lilly response to 483

Redacted

03/13/01 - 21-253 - NTF re: telephone discussion w/ Steve Hardeman on bldg 105/action letter
03/14/01 - 21-253 - Fax copy of Warning Letter to Steve Hardeman in response to his 3/13 telephone request
03/14/01 - 21-253 - E-mail to Steve Hardeman of response to 1-19-01 FDA fax request
03/15/01 - 21-253 - Submitted response to 1-19-01 FDA fax request for oral Phase 1-Phase 4 data (included all pertinent data except for Japanese Phase 1 data)

03/15/01 -	21-253 - QA/Manufacturing meeting w/ FDA Detroit District Office re: PAI issues
03/16/01 -	28,705 – Submitted CM&C amendment
03/19/01 -	21-253 - NTF re: discussion w/ Steve Hardeman on approvable letter
03/19/01 -	60,701 – Submitted F1D-EW-LOBE(b)
03/20/01 -	Submitted export authorization for additional quantities of olanazapine pamoate to ship to Croatia
03/21/01 -	20-592 (S014) – Received FDA approval letter (dated 3/13/01)
03/23/01 -	21-253 - Submitted follow-up report of Japanese Phase 1 data completing response to 1-19-01 fax request; also sent e-mail copy
03/28/01 -	28,705 - Submitted Final Study Report F1D-MC-HGFU
03/29/01 -	28,705 – Submitted HGJJ(a) and HGJN(a)
03/29/01 -	21-253 – Received FDA approvable letter
03/30/01 -	21-253 – Submitted notification of intent to amend NDA
03/30/01 -	28,705 – Cross-reference letter for Dr. Kane
04/11/01 -	28,705 – Cross-reference letter for Dr. Delbello
04/12/01 -	20-592, 21-086 – Submitted Mortality/Suicidality Report and datasets
04/16/01 -	60,701 – CM&C amendment for OPM (new vehicle)
04/19/01 -	28,705 – Submitted Final Study Report F1D-MC-HGHQ
05/03/01 -	E-mail to Michelle Limoli to check on status of olanzapine depot export authorization for additional quantities to Croatia (March 20, 2001)
05/04/01 -	60,701 – Submitted OPM Toxicology and ADME reports for 3 month rat and 6 month dog studies
05/04/01 -	21-253 – Receipt of FDA letter responding to Lilly March 9th CMC submission and requesting additional information
05/07/01 -	Fax and e-mail to Michelle Limoli to request approval of olanzapine depot export authorization for additional quantities to Croatia (March 20, 2001)
05/08/01 -	20-592, 21-086 – E-mail request from Dr. Andrew Mosholder asking for clarification in our abbreviations within datasets provided with the 4/12/01 Mortality/Suicidality Report (NTF)
05/08/01 -	28,705 – Submitted F1D-MC-HGJN(b)
05/10/01 -	20-592, 21-086 – E-mail request from Dr. Andrew Mosholder asking for clarification in the units for the duration variable within datasets provided with the 4/12/01 Mortality/Suicidality Report (NTF)
05/10/01 -	21-253 – Submitted ZYPREXA labeling summary
05/14/01 -	20-592, 21-086 – E-mail request from Dr. Andrew Mosholder asking for clarification in inclusion of trials with IM olanzapine within datasets provided with the 4/12/01 Mortality/Suicidality Report (NTF)

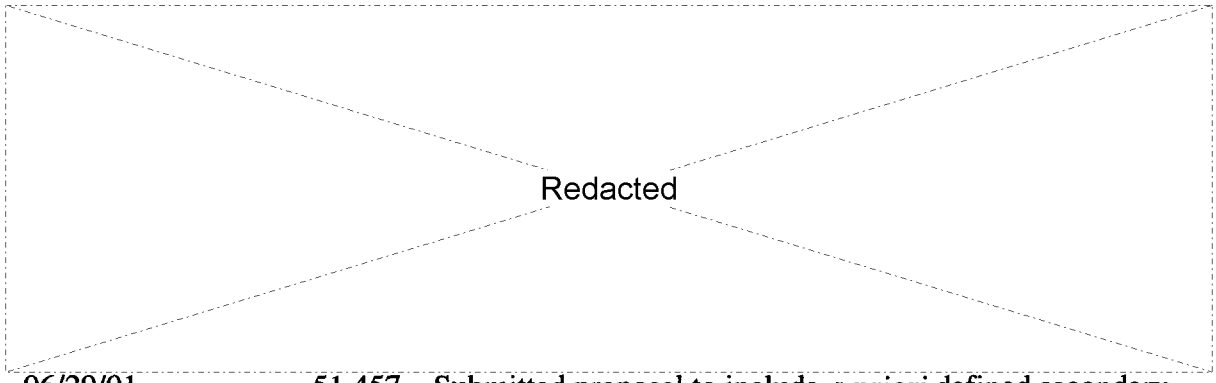
05/15/01 - Received e-mail from Michelle Limoli granting approval for additional quantities of olanzapine depot for export to Croatia (LOBE)

05/16/01 - 28,705 – Submitted F1D-MC-S013(a)

05/25/01 - 20-592, 21-086 – Received approval of Changes Being Effected Labeling supplements [20-592; S-012 and S-013: 21-086; S-001 and S-002]

06/01/01 - 28,705 – Submitted Clinical Study Report for F1D-MC-HGHD

06/04/01 - 60,701 – Submitted meeting request for preclinical/clinical plan discussion regarding OPM depot; e-mailed meeting request to Steve Hardeman



06/29/01 - 51,457 – Submitted proposal to include *a priori* defined secondary efficacy measures in psychosis due to AD labeling

07/11/01 - 28,705 – Submitted Protocol F1D-MC-HGJX

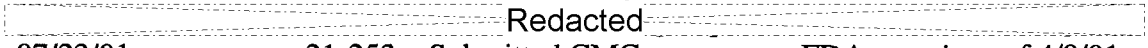
07/12/01 - NTF: E-mailed explanation regarding increased numbers of hematologic adverse event reports to Steve Hardeman

07/16/01 - 60,701 – E-mailed and received list of FDA participants for July 31, 2001 meeting with the Division from Steve Hardeman

07/17/01 - 60,701 – E-mailed Steve Hardeman Briefing Document to support July 31, 2001 meeting with the Division

07/17/01 - 60,701 – Submitted Olanzapine Depot Briefing Document to support July 31, 2001 meeting with the Division

07/17/01 - 21-153 – NTF re: e-mail from Steve Hardeman with FDA comments on IM labeling



07/23/01 - 21-253 – Submitted CMC response to FDA questions of 4/9/01 meeting and 5/4/01 written request

07/25/01 - 28,705 – Submitted Clinical Study Synopsis – Allelic Variation in Schizophrenia

07/26/01 - 28,705 – Submitted Protocol HGHJ

07/26/01 - 21-253 – Submitted response to FDA 7/17/01 e-mail comments on IM labeling

07/26/01	28,705 - Submitted Protocol F1D-US-HGJT
08/06/01 -	28,705 - Submitted correspondence on decision to not conduct interim analyses with Redacted F1D-MC-HGHL; e-mailed to Doris Bates on 08/08/01
08/08/01 -	28,705 - Submitted F1D-US-HGHQ final study report with extension phase results
08/09/01 -	20-592 - NTF: E-mailed marketing status of Zyprexa 20 mg tablets to Gladys Holley, Orange Book office, per telephone request
08/8 & 9/01	21-253 – NTF re: e-mail interactions between J Roth and S Hardeman providing "annotated" IM labeling to FDA
08/10 & 14/01	21-253 – NTF re: FDA's IM labeling counterproposal in response to Lilly April 19th response to approvable letter
08/14-17/01	21-253 – NTF re: e-mail interactions between J Roth and G Dubitsky on D&A and Drug Interactions texts of IM labeling
08/15/01 -	FDA export authorization for Protocol HGHJ
08/21/01 -	21-253 – NTF re: e-mail interactions between J Roth and G Dubitsky accepting Division's proposed Drug Interactions text
08/22/01 -	21-253 – NTF re: e-mail from J Roth to G Dubitsky re: FDA "clean" copy of IM labeling
08/24/01 -	21-253 – NTF re: e-mail interactions between J Roth and G Dubitsky on FDA "clean" copy of IM labeling
08/27/01 -	28,705 - NTF: Received e-mail from Doris Bates regarding statistical reviewers comments on interim analysis plans for Redacted HGHL
08/27/01 -	21-253 – NTF re: e-mail from Greg Dubitsky to John Roth of final agreed upon IM labeling (Version 8-27-01)
08/29/01 -	60,701 - Submitted Meeting Minutes for July 31, 2001 meeting with Division; e-mailed to Steve Hardeman on 08/30/01
08/29/01 -	20-592 - Received e-mail request from Dr. Andrew Mosholder regarding clarification of 2 studies included in clinical trial datasets for suicide/mortality report submitted on April 12, 2001; provided response via e-mail
08/30/01 -	60,701 - Submitted follow-up from July 31, 2001 meeting regarding definition of non-inferiority for Protocol F1D-MC-HGKA; e-mailed to Steve Hardeman
09/06/01 -	28,705 - Submitted F1D-MC-HGIM Clinical Study Report
09/26/01 -	28,705 – Submitted F1D-MC-HGJX Addendum (1)—DNA Banking
10/02/01 -	60,701 – CM&C amendment for OPM
10/03/01 -	60,701 –Meeting request with Division to discuss toxicology plan
10/08/01 -	21-086 – CBE Supplement re: changes to analytical procedures
10/12/01 -	60,701 – Submitted F1D-EW-LOBE Addendum (5)---increase single dose up to 450 mg
10/16/01 -	21-086 – FDA Acknowledgement of CM&C supplement (S003)

10/30/01-	60,701 - Submitted F1D-EW-LOBE(c) –increase multiple doses of up to 450 mg
	Redacted
11/09/01 -	20-592 – Received FDA CBE-30 Supplement letter
	Redacted
11/21/01 -	60,701 – Meeting confirmation letter with briefing document to discuss toxicology requirements for Dec. 6, 2001 meeting
11/21/01 -	20-592 – S-015 Supplement Amendment
11/21/01 -	20-592 – Special Supplement-Package Component
	Redacted
11/28/01 –	20-592 Periodic Adverse Drug Experience Report
11/28/01 -	20-592 Annual Report
	Redacted
12/10/01 -	20-592 – Received FDA CBE-O Supplement
12/10/01 -	20-592 – Received FDA Pediatric Study Request indicating incomplete
12/11/01 -	28,705 Proposal for inclusion of Secondary Efficacy Measures
12/12/01 -	28,705 – FDA Letter-Comments of Clinical & Statistical Review (Katz)
	Redacted
12/18/01 -	28,705 – Submitted meeting minutes for 11/9/01 FDA meeting
12/19/01 -	20-592 - Submitted Special Supplement-Package component
12/20/01 -	28,705 – Meeting confirmation 01/16/02
12/20/01 -	20-592 – Submitted Waiver request to submit postmarketing periodic safety reports (PSUR)
01/03/02 -	28,705 – Protocol Amendment
01/09/02 -	28,705 – Received FDA meeting minutes for 11/9/01 FDA meeting
01/11/02 -	20-592 and 21-086 – Submitted labeling supplement
	Redacted
01/22/02 -	20-592 – S016 (CM&C) approval letter
	Redacted
01/28/02 -	20-592 – Submitted proposal to amend FDA's written request for Pediatric Studies
01/29/02	20-592 – FDA approved supplemental new drug application
	Redacted
02/21/02 -	28,705 – E-mail request from Doris Bates for list of Lilly attendees at Feb. 8, 2002 meeting and copy of slides from meeting
02/26/02 -	28,705 – Submitted F1D-MC-HGJX(a)
02/26/02 -	28,705 – E-mailed Doris slides from Feb. 8, 2002 meeting

Redacted

03/01/02 - 28,705 – E-mailed Doris meeting minute for Feb. 8, 2002 meeting and request for status on July 12, 2001 proposal for inclusion of secondary endpoints in bipolar maintenance labeling

03/05/02 - 28,705 - Cross-reference letter for Dr. Kent Hutchinson

Redacted

03/07/02 - 28,705 – E-mail from Doris with FDA meeting minutes from Feb. 8, 2002 meeting

03/03/02 - 28,705 – E-mail to Doris clarifying process to amend statements in FDA meeting minutes

03/13/02 - 28,705 – IRB discontinuation of Dr. Richard Wang (F1D-MC-HGJN)

Redacted

03/21/02 - 28,705 – Phone discussion with Doris Bates regarding bipolar program

03/22/02 - 28,705 – E-mail to Doris documenting action items discussed during March 21, 2002 telephone conversation

04/04/02 - 20-592 – Amendment to S015 (CM&C)

Redacted

04/11/02 - 28,705 – Meeting request for pre-NDA meeting (combination bipolar mania and bipolar maintenance efficacy supplements)

04/02/02 - 28,705 – E-Mail from Steve follow-up questions-# of patients for safety

Redacted

04/12/02 - E-mail to Dr. Laughren with report on Japan hyperglycemia cases including copies of MedWatch reports

04/13/02 - E-mail to Dr. Paul Seligman (Office of Pharmacoepidemiology and Statistical Sciences) with report on Japan hyperglycemia cases including copies of MedWatch reports

04/16/02 - 28,705 – E-mailed meeting request letter (dated 04/11/02) for pre-NDA meeting to Doris

04/17/02 - 28,705 – E-mail from Doris scheduling pre-NDA meeting

04/18/02 - 28,705 – E-mail from Doris scheduling pre-NDA meeting

04/18/02 - 28,705 – E-mail to Doris with need to re-schedule pre-NDA meeting

04/25/02 - 20-592 – Non-approvable letter for S015 (CM&C)

04/25/02 - 28,705 – E-mail to Steve with follow-up report on Japan hyperglycemia cases

04/26/02 - 28,705 – E-Mail to Steve Re Pediatric Written Agreement

05/03/02 - NTF Telephone discussion with Dr. Andreason regarding tampering of Zyprexa bottles

05/10/02 -	20-592 – Correspondence on agreements reached during May 9, 2002 telephone conversation regarding non-approvable letter for S015 (CM&C)
05/14/02 -	28,705 – Submitted briefing document for May 30, 2002 pre-NDA meeting (and e-mailed notice to Doris)
05/15/02 -	E-mail request from Steve for copy of Prescription Event Monitoring report for olanzapine from UK Drug Safety Research Unit
05/15/02 -	28,705 – E-mail from Steve July calendar
05/15/02 -	28,705 – E-mail from Steve July calendar
05/15/02 -	28,705 – E-mail from Steve July calendar
05/15/02 -	28,705 – E-mail from Steve July calendar
05/29/02 -	NTF E-mail from Steve confirming receipt of Prescription Event Monitoring report for olanzapine from UK Drug Safety Research Unit
05/29/02 -	20-592, 21-086 – Submitted Periodic Safety Update Report (PSUR)
06/03/02 -	Export Authorization approval letter for China (F1D-GH-S036)
06/03/02 -	28,705 – E-mail to Doris with proposal on what to include in bipolar maintenance supplemental NDA regarding results from F1D-MC-HGGW (follow-up from May 30, 2002 pre-NDA meeting discussion)
06/03/02 -	E-mail to Michelle Limoli requesting status of export authorization request for China
06/07/02 -	28,705 – Submitted Study Reports for F1D-MC-HGEF, F1D-MC-HGGC, and F1D-LC-HGFN
06/10/02 -	28,705 – Submitted meeting minutes from May 30, 2002 pre-NDA Meeting
06/10/02 -	28,705 – Proposal for inclusion of secondary efficacy measures in bipolar maintenance labeling
06/11/02 -	28,705 – E-mail to Doris giving notice of June 10, 2002 submissions (meeting minutes and proposal for inclusion of secondary efficacy measures)
	Redacted
06/17/02 -	28,705 – NTF E-mail to Doris acknowledging voice mail on acceptability of proposal regarding HGGW results by Dr. Racoosin
	Redacted
06/21/02 -	28,705 – E-mail from Steve providing guidance on transfer of study records for F1D-MC-HGGF
06/21/02 -	20-592 – E-mail to Dr. Levin regarding electronic submission proposals from May 30, 2002 pre-NDA meeting
06/24/02 -	20-592 – E-mail response from Dr. Levin with agreement on electronic submission proposals

06/24/02 - 28,705 – Correspondence to correct error in F1D-MC-HGGI locked database

Redacted

06/25/02 - 20-592 – E-mail question to Doris regarding risk management plan requirements for supplemental NDAs

06/27/02 - 20-592 – E-mail to Steve giving notice of PSUR amendment (cardiac failure cases)

06/28/02 - 20-592, 21-086 – Submitted PSUR amendment (cardiac failure cases)

06/28/02 - 28,705 – Last question-NCDEU presentations

07/03/02 - 20-592, 21-086 – FDA atypical antipsychotic class request for review of cerebrovascular adverse events in patients with dementia (and received via e-mail from Steve)

07/08/02 - 28,705 – NTF E-mail from Doris: FDA Meeting Minutes from May 30, 2002 pre-NDA meeting (combination bipolar mania and bipolar maintenance)

Redacted

08/08/02 - 20-592 – E-mail to Lee Ripper regarding financial disclosure proposal for bipolar maintenance supplement

Redacted

08/13/02 - 20-592 – NTF E-mail to Doris documenting Aug. 13, 2002 telephone conversation with Lee Ripper on financial disclosure proposal for bipolar maintenance supplement

08/13/02 - 20-592 – E-mail response from Doris regarding financial disclosure proposal

08/15/02 - 28,705 – E-mail from Steve Pediatric Question

08/30/02 - 28,705 – Submitted Protocol F1D-EW-LOBU

09/04/02 - 28,705 – E-mail from Steve Glucose Metabolism Meeting Request

09/11/02 - 20-592 – FDA atypical antipsychotic class request for detailed datasets from schizophrenia trials

09/12/02 - 28,705 – Cross-reference letter for Dr. Stephen Silberstein

09/16/02 - 20-592 – Electronic submission of efficacy supplement (use in combination with lithium or valproate for treatment of bipolar mania)

09/17/02 - 20-592 – E-mail to Doris giving notice of Sept. 16, 2002 efficacy supplement submission and informing her of future amendment

09/18/02 - 28,705 – E-mail from Steve Pediatrics Written Request letter-outpatients

09/19/02 -	20-592 – E-mail from Doris asking whether categorical exclusion of environmental assessment was included in Sept. 16 sNDA
09/20/02 -	20-592 – E-mail to Doris proposing to include categorical exclusion of environmental assessment in amendment to Sept. 16 sNDA
09/20/02 -	20-592 – E-mail from Doris agreeing on 09/20/02 e-mail proposal
	Redacted
09/26/02 -	20-592 – Voice mail from Doris indicating that filing meeting for Sept. 16 sNDA is scheduled for 9AM Oct. 30.
09/26/02 -	28,705 – E-mail from Steve Desk copis for 10/17 meeting
09/27/02 -	20-592 – E-mail from Doris indicating that Dr. Earl Hearst is medical reviewer assigned to 09/16/02 sNDA
09/30/02 -	20-592 – E-mail from Doris indicating that Dr. Veneeta Tandon is biopharm reviewer assigned to 09/16/02 sNDA
	Redacted
10/15/02 -	28,705 – Cerebrovascular adverse event request-need clarification
10/15/02 -	28,705 – E-mail from Steve Questions on FDA suicide data
10/15/02 -	28,705 – E-mail from Steve glucose metabolism meeting
10/23/02 -	28,705 – E-mail from Steve Follow-up questions on "VA" study from Oct 15 conference w/Dr. Katz
10/24/02 -	28,705 – E-mail from Steve Follow-up questions on "VA" study from Oct 15 conference w/Dr. Katz
10/25/02 -	28,705 – E-mail from Steve – Catch-up on yesterday's actions
10/30/02 -	20-592 – Voice mail from Doris indicating that the Sept. 16 submission (Zyprexa in combination with lithium or valproate in the treatment of bipolar mania) has been filed and given supplement number 18
10/31/02 -	28,705 – Submitted Protocols F1D-MC-HGIN and F1D-MC-HGIU
11/04/02 -	20-592 – Received acknowledgement and filing letter for S018
11/06/02 -	20-592 – E-mail from Doris indicating that the filing meeting for bipolar maintenance sNDA has been scheduled for January 17, 2003 at 11AM.
11/06/02 -	28,705 – Submitted Clinical Study Reports for F1D-MC-HGFI and F1D-MC-S013
11/12/02 -	20-592 (S018) – NTF Received call from Sherita McLamore requesting submission of amendment regarding environmental assessment
11/13/02 -	20-592 (S018) – Submitted amendment letter requesting categorical exclusion from environmental assessment requirement
11/18/02 -	20-592 – NTF Received Zyprexa product complaint call from Minneapolis Field Office
11/20/02 -	20-592 (S018) – NTF Received e-mail request from Dr. Earl Hearst

11/20/02 -	20-592 – Electronic submission of efficacy supplement (Long-term treatment of bipolar I disorder)
11/22/02	20-592 (S-020):- Submitted labeling supplement under 314.70(c); back-highlighting PREXA in yellow and adding tamper resistant information to label
11/27/02 -	20-592 and 21-086 – Submitted PSUR-10
12/03/02 -	28,705 – E-mail from Steve-Investigator IND Question
12/04/02 -	20-592 (S018) – NTF E-mailed response to Dr. Hearst question (Nov. 20, 2002)
12/10/02 -	28-705 – E-mail from Steve-Question on datasets
12/11/02 -	20-592 and 21-086 – Submitted response to mortality request
12/12/02 -	20-592 – E-mail from Doris indicating Dr. Teresa Podruchny has been assigned as the medical reviewer for bipolar maintenance sNDA
12/12/02 -	20-592 and 21-086 – E-mailed Steve alerting him to PSUR-10 amendment submission
12/13/02 -	20-592 and 21-086 – Submitted amendment to PSUR-10
12/16/02 -	20-592 (S020) – Submitted additional information to package labeling supplement
	Redacted
12/19/02 -	20-592 (S019) – NTF Received call from Sherita McLamore requesting location of environmental assessment and confirmation that drug product and drug substance were unchanged
12/20/02 -	20-592 (S020) – Submitted additional information to package labeling supplement
01/10/03 -	20-592 (S017) and 21-086 (S004) – Received approvable letter for January 11, 2002 labeling supplement
01/13/03 -	20-592 (S019) – E-mail from Doris requesting SAS code for primary efficacy analyses from HGHL, HGHT and HGFU.
01/17/03 -	20-592 (S019) – Telephone call from Doris: application was filed today.
01/29/03 -	20-592 (S018) – E-mail from Dr. Hearst requesting clarification on patient exposures in HGFU extension report.
01/29/03 -	20-592 and 21-086 – Submitted additional CVA information
02/10/03 -	20-592 (S019) – Filing letter received
02/24/03 -	20-592 (S018 and S019) – NTF: Dr. Bates called and provided update on review status
03/06/03 -	20-592 (S017) and 21-086 (S004) – Submitted FPL in response to 01/10/03 approvable letter
03/10/03 -	20-592 and 21-086 – Submitted clarification regarding glucose TED analysis
03/18/03 -	20-592 and 21-086 – E-mailed Steve with proposed submission strategy for labeling supplement
03/31/03 -	20-592 and 21-086 – Submitted labeling supplement (receptor binding, PK race and Nursing Mothers)

04/01/03 -	20-592 and 21-086 – E-mailed Steve WORD version of proposed labeling for 3/31/03 submission
04/07/03 -	20-592 (S018 and S019) – NTF: Dr. Bates called and provided update on review status.
04/09/03	28,705- Submitted BD for CIAS meeting April 23, 2003
	Redacted
04/23/03 -	21-086 – NTF: Received request from FDA (Michael Folkendt, Office of Chemistry) for samples of Zydis to conduct FDA internal exploratory study
	Redacted
05/01/03 -	28,705 – Submitted CSR HGAO extension phase
	Redacted
05/14/03	28,705- Submitted meeting minutes (CIAS) FDA meeting 4/23/03
05/23/03 -	28,705 – CIB submitted
05/27/03	20-592 (S018 and S019) – E-mail to Doris requesting status update
05/28/03	20-592 (S020): FDA AE letter for bottle label change. Provided additional requests with regard to educational program of Zyprexa/Zyrtec medication errors.
05/29/03	20-592 – FDA letter-postmarketing study commitment (schizophrenia relapse) complete
05/29/03 -	20-592 (S018) – E-mail request from Doris for current labeling and proposed labeling (clean and mock-up)
05/29/03 -	20-592 (S018 and S019) – Telephone discussion with Doris re: status
06/03/03	20-592 (S020) – Received approvable letter (medication errors) includes list of deficiencies to be addressed
06/06/03 -	20-592 (S018) – NTF: Provided 5/29/03 labeling request by e-mail
06/09/03	60-701-Response to clinical protocol assessment request (Katz)
06/09/03 -	28,705 – Submitted F1D-MC-HGJX Clinical Study Report
06/11/03-8/14/03	28,705-Emails regarding upcoming pre-NDA meeting for CIAS
06/20/03 -	28,705 – Submitted F1D-MC-HGHJ Clinical Study Report
06/20/03 -	20-592 – E-mailed Steve Hardeman and submitted hard copy of glucose update
06/30/03 -	20-592 (S018 and S019) – E-mail communications with Doris regarding status
07/01/03 -	28,705 – Submitted Protocols for F1D-MC-HGLB and F1D-US-HGLF
07/07/03 -	20-592 (S018) – NTF: Received labeling via e-mail from Doris
07/08/03 -	20-592 (S018) – E-mailed Doris revised labeling
07/09/03 -	20-592 (S018) – Received labeling counterproposal from Doris and e-mailed Doris revised labeling
07/10/03 -	20-592 (S018) – Approval letter received

07/10/03 -	20-592 – Received request for glucose lab values related to 6/20/03 glucose update submission
07/18/03 -	20-592 (S019) – Received request for labeling
07/23/03 -	20-592 (S018) – Submitted FPL
07/24/03 -	20-592 (S019) – Responded to labeling request via e-mail
07/25/03 -	20-592 (S019) – Question received from medical reviewer and question received from statistician
	Redacted
07/31/03 -	20-592 (S019) – NTF: Responded via e-mail to FDA questions received on 7/25/03
07/31/03	28,705- Submit pre-NDA meeting package CIAS
08/04/03 -	20-592 – Responded to 07/10/03 FDA request for glucose lab values
08/05/03 -	20-592 and 21-086 – Submitted labeling supplement (overdose and excipient)
08/07/03 -	20-592 (S019) – Submitted HGHL Addendum (2); e-mailed to Drs. Podruchny and Kelly
08/11/03 -	20-592 (S019) – Received request from Dr. Andreason via e-mail
08/12/03 -	20-592 (S019) – NTF: Responded via e-mail to Dr. Andreason request
08/25-08/28/03 -	28,705 - Email communications with FDA regarding outcome of our CIAS pre-NDA meeting on 8/14/03.
09/03/03 -	20-592 – CM&C CBE-30 Supplement
09/05/03 -	20-592 (S017) and 21-086 (S004) – Letter that acknowledges labeling supplement superceded by approval of NDA 20-592 (S018) on 7/10/03
09/15/03 -	20-592 and 21-086 – Received letter from FDA requesting inclusion of warning regarding hyperglycemia and diabetes in labeling