



### Cetuximab Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
5/10/1994	TCR	From: K. Krantz To: Dr. R. Cohen	Outcome of study; Submission of IMCL's plans for C225 and pre-IND meeting	1
5/13/1994	TCR	From: K. Schneider To: J. Archbold	Submission of to	1
7/6/1994	TCR	From: K. Krantz To: D. Schneider	C225 pre-IND meeting plans; Compassionate IND close-out	1
7/22/1994	Letter	From: ImClone To: FDA	Pre-IND Meeting Document for C225 - aEGFrAb Anti-Epidermal Growth Factor Receptor Chimeric Antibody	1
8/11/1994	TCR	From: K. Krantz To: D. Green	C225 Toxicology testing	1
8/19/1994	TCR	From: F. Kaltovitch To: K. Krantz	C225 Pre-IND Review and Meeting	1
9/9/1994	TCR	From: Dr. R. Nordin To: K. Krantz, J. Gilly	C225 pre-IND Product Reviewer's Comments	1
10/14/1994	Amendment 000	Kathryn Zoon	Initial IND application (Release Protocol Lot 423704)	1
10/20/1994	Letter	Kathryn Zoon	Additional copies of Initial IND	1
10/20/1994	TCR	From: K. Schneider To: K. Krantz	C225 #5804	1
11/3/1994	Letter	From: FDA To: K. Krantz	October 26, 1994 Letter advising the assignment of an IND number for C225 (BB-IND 5804)	1
1/5/1995	Letter	From: FDA To: K. Krantz	December 30, 1994 Letter regarding comments following review of IND 5804 initial submission	1
2/6/1995	Amendment 001	Kathryn Zoon	Information Amendment - CMC (Release Protocol Lot 500301), Protocol Amendment - Change in Protocol (Version 2.0 CP02-9401) and New Investigator	1
3/10/1995	Amendment 002	Kathryn Zoon	Protocol Amendment - New Protocol (CP02-9502, CP02-9503)	1
3/23/1995	Amendment 003	Kathryn Zoon	General Correspondence - Change in regulatory contact	1
4/4/1995	TCR	From: J. Gilly To: K. Schneider	Status of submission IND #5804, Serial No. 002	1
4/10/1995	TCR	From: J. Gilly To: K. Schneider	Review of protocols CP02-9502 and CP02-9503	1
4/13/1995	TCR	From: M. Fauntleroy To: J. Gilly	Protocol CP02-9502 and CP02-9503C225, Anti-EGF receptor chimeric antibody	1
4/17/1995	Amendment 004	Kathryn Zoon	Response to FDA Request for Information - product, manufacturing, clinical; Protocol Amendment - Change in Protocol (CP02-9401, Version 3.0)	1
7/24/1995	Amendment 005	Kathryn Zoon	Information Amendment - Chemistry/Microbiology (Release Protocol Lot 950012)	1
8/3/1995	Amendment 006	Kathryn Zoon	Initial Safety Report - Mfg. Control #95/02/00005	1
8/24/1995	Amendment 007	Kathryn Zoon	Initial Safety Report - Mfg. Control #95/02/00007	1
9/5/1995	Amendment 008	Kathryn Zoon	Protocol Amendment - Change in Protocol CP02-9502, Version 3.0 - Amendments 1 & 2; CP02-9503, Version 3.0	1
9/12/1995	Amendment 009	Kathryn Zoon	Protocol Amendment - Change in Protocol (CP02-9503)	1
11/20/1995	TCR	From: Dr. R. Justice To: J. Gilly	Patient #1302-UVA-CP02-9502, compassionate use	1

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11/20/1995	TCR	From: J. Gilly To: K. Schneider	Patient #1302-UVA-CP02-9502, compassionate use	1
11/21/1995	TCR	From: K. Schneider To: J. Gilly	Patient #1302-UVA-CP02-9502, compassionate use	1
11/29/1995	Amendment 010	Kathryn Zoon	Initial Safety Report - Mfg. Control #95/02/00009	1
11/30/1995	Amendment 011	Kathryn Zoon	Protocol Amendment - New Protocol (CP02-9502, Version 3.1)	1
12/8/1995	Amendment 012	Kathryn Zoon	Initial Safety Report - Mfg. Control #95/02/00011	1
12/15/1995	TCR	From: J. Archbold To: K. Schneider	Protocol changes to FDA/CBER	1
12/18/1995	Amendment 013	Kathryn Zoon	Protocol Amendment - New Protocol (CP02-9504)/Change in Protocol (CP02-9503, Amendments 4 & 5)	1
1/15/1996	Amendment 014	Kathryn Zoon	Annual Report	1
2/27/1996	Regulatory file	J. Gilly	Protocol CP02-9502 - Patient #3407	1
3/13/1996	Amendment 015	Kathryn Zoon	Protocol Amendment - New Protocol (CP02-9605)/Change in Protocol (CP02-9504, Versions 3.0 & 4.0)	1
4/18/1996	TCR	From: J. Archbold To: K. Schneider	To inquire who the reviewer for 5804 IND and what procedure to follow for teleconference to discuss comments (12/4/94 letter)	1
4/24/1996	Amendment 016	Kathryn Zoon	Request for Telephone Conference	1
5/9/1996	Amendment 017	Kathryn Zoon	General Correspondence - single patient exemption	1
5/9/1996	TCR	From: J. Gilly To: K. Schneider	Single patient exemption for C225 therapy (compassionate use)	1
5/9/1996	TCR	From: K. Schneider To: J. Gilly	Single patient exemption for C225 therapy (compassionate use)	1
5/10/1996	TCR	From: J. Gilly To: K. Schneider	Single patient exemption for C225 Therapy (Compassionate Use)	1
5/15/1996	Amendment 018	Kathryn Zoon	Protocol Amendment - New Protocol (CP02-9606)	1
5/15/1996	TCR	From: K. Schneider To: J. Gilly	Submission Serial No. 016-Re: Request for telephone conference	1
5/30/1996	Amendment 019	Kathryn Zoon	Other - Final Study Report (CP02-9401)	1
6/18/1996	Amendment 020	Kathryn Zoon	Initial Safety Report - Mfg. Control #95/02/00018	1
6/18/1996	TCR	From: Dr. J. LaBorda To: J. Gilly	IND Amendment letter: April 24, 1996; Serial No. 016 (request for phone conference)	1
6/21/1996	TCR	From: J. Gilly To: Dr. J. LaBorda, Dr. E. Bonvini	Phone conference pertaining to IND Amendment letter: April 24, 1996, Serial No. 016	1
7/1/1996	Amendment 021	Kathryn Zoon	Information Amendment - CMC (Release Protocol Lot 960159)	1
8/27/1996	Amendment 022	Kathryn Zoon	Information Amendment - CMC (Release Lot 960223); Protocol Amendment - Change in Protocol (CP02-9503, Version 7.0; CP02-9605, Version 2.0)	1
11/1/1996	Amendment 023	Kathryn Zoon	Protocol Amendment - Change in Protocol (CP02-9504, Amendment letter)/New Protocol (CP02-9607); Information Amendment - CMC (Release Lot 960275)	1
11/1/1996	TCR	From: J. Gilly To: K. Schneider	Submission Serial No. 023-Re: Clinical protocol IMCL CP02-9607	1

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12/3/1996	TCR	From: K. Schneider To: J. Gilly	Submission Serial No. 023-Re: Clinical protocol IMCL CP02-9607	1
12/17/1996	Amendment 024	Kathryn Zoon	Initial Safety Report - Mfg. Control #96/02/00023	1
1/10/1997	Amendment 025 (via Fax)	From: J. Gilly To: K. Schneider	General Correspondence - single patient protocol exemption (CP02-9504)	1
1/10/1997	TCR	From: J. Gilly To: K. Schneider	Fax submission Serial No. 025-Re: Clinical protocol IMCL CP02-9504 single patient exemption	1
1/14/1997	Fax	From: J. Archbold To: Dr. B. Parker	Fax submission Serial No. 025-Re: Clinical protocol IMCL CP02-9504 single patient exemption	1
1/14/1997	TCR	From: Dr. B. Parker To: J. Falcey	Fax submission Serial No. 025-Re: clinical protocol IMCL CP02-9504 single patient exemption (forwarded)	1
1/14/1997	TCR	From: Dr. B. Parker To: J. Falcey	Fax submission Serial No. 025-Re: clinical protocol IMCL CP02-9504 single patient exemption & has reviewed the protocol)	1
1/15/1997	Amendment 025	Kathryn Zoon	General Correspondence - Hard copy of faxed documents	1
1/15/1997	TCR	From: K. Schneider To: J. Gilly	C225 Review Team	1
1/28/1997	Amendment 026	Kathryn Zoon	Annual Report	1
3/21/1997	Amendment 027	Kathryn Zoon	Other - Final Study Report (CP02-9502)	1
4/18/1997	Amendment 028	Kathryn Zoon	Information Amendment - CMC (Release Lot 960430); Protocol Amendment - Change in Protocol (CP02-9607, Version 4.0; CP02-9608, Version 4.0)	1
5/16/1997	TCR	From: K. Schneider To: J. Gilly	NBC Report regarding ImClone products	1
5/27/1997	Amendment 029	Kathryn Zoon	Initial Safety Report - Mfg. Control #97/02/00028	1
5/30/1997	Amendment 030	Kathryn Zoon	Follow-up to a Written IND Safety Report - Mfg. Control #97/02/00028	1
6/16/1997	Amendment 031	Kathryn Zoon	Protocol Amendment - Change in Protocol (CP02-9504, Version 6.0); Other - FDA Contact Authorization	1
7/8/1997	Amendment 032	Kathryn Zoon	Protocol Amendment - New Protocol (CP02-9709, Version 1.0)	1
7/29/1997	Fax	From: G. Toolan To: K. Schneider	Information regarding BB-IND 5804, experienced by Patient 1101 in CP02-9709 (filed as Serial No. 032)	1
7/29/1997	TCR	From: J. Gilly, G. Toolan To: K. Schneider	3-day Telephone Report regarding :	1
7/30/1997	Amendment 033	Kathryn Zoon	Protocol Amendment - Change in Protocol (CP02-9608, Version 5.0; CP02-9607, Version 4.1; CP02-9605, Versions 3.0 & 4.0); Protocol Amendment - New Investigator (CP02-9605, Information Amendment - Chemistry & Microbiology (Release protocol Lot 970002)	1
8/5/1997	Amendment 034	Kathryn Zoon	Initial Safety Report - Mfg. Control #97/02/00034	1
8/25/1997	Amendment 035	Kathryn Zoon (Attn: Sharon Sickafuse)	General Correspondence - Single patient exemption protocol (CP02-9712)	1

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8/25/1997	TCR	From: J. Gilly, G. Toolan To: S. Sickafuse	Protocol CP02-9712 Compassionate use	1
8/27/1997	TCR	From: J. Gilly, G. Toolan To: S. Sickafuse	Report on grade 1 toxicity	1
9/2/1997	TCR	From: G. Toolan To: S. Sickafuse	Compassionate Use Protocol	1
9/2/1997	TCR	From: K. Schneider To: G. Toolan	Compassionate Use Protocol-CP02-9712	1
9/4/1997	Amendment 036	Kathryn Zoon	Initial Safety Report - Mfg. Control #97/02/00037	1
9/4/1997	TCR	From: Dr. B. Parker To: G. Toolan	Compassionate Use Protocol-CP02-9712	1
9/15/1997	Amendment 037	Kathryn Zoon	Protocol Amendment - Change in protocol (CP02-9712)	1
10/21/1997	Amendment 038	Kathryn Zoon	General Correspondence - background information re: EGFr expression as requested by (clinical reviewer)	1
11/14/1997	Amendment 039	Kathryn Zoon	Protocol Amendment - New Protocol (CP02-9710, Version 3.0, ...); Other - Meeting Request	1
11/14/1997	Other	Kathryn Zoon	Additional Copies of Amendment 039	1
11/17/1997	TCR	From: S. Sickafuse To: G. Toolan	Serial No. 039-Teleconference request	1
11/20/1997	TCR	From: S. Dayton To: G. Toolan	Scheduling of teleconference	1
11/26/1997	TCR	From: G. Toolan To: S. Sickafuse	Report: ... in CP02-9608	1
12/1/1997	Amendment 040	Kathryn Zoon	Protocol Amendment - Change in Protocol (CP02-9504, Version 6.0; CP02-9608, Version 6.0); Information Amendment - Chemistry & Microbiology (Release Protocol Lot 970311)	1
12/5/1997	Amendment 041	Kathryn Zoon	Initial Safety Report - Mfg. Control #97/02/00041	1
12/15/1997	Amendment 042	Kathryn Zoon	Initial Safety Report - Mfg. Control #97/02/00042	1
12/23/1997	Amendment 043	Kathryn Zoon	General Correspondence - Teleconference agenda, issues list and meeting attendees	1
12/29/1997	Amendment 044	Kathryn Zoon	Protocol Amendment - Change in Protocol (CP02-9607, Version 5.0); Protocol Amendment - New Investigator (CP02-9608, ... CP02-9710, ...)	1
1/6/1998	TCR	From: G. Toolan To: S. Sickafuse	Verify telephone number for teleconference initiated by ImClone	1
1/12/1998	Amendment 045	Kathryn Zoon	FDA Request for Information (Response to FDA's letter of 12/11/97 re: human blood-derived products)	1
1/21/1998	Amendment 046	Kathryn Zoon	General Correspondence - Meeting Minutes	1
2/2/1998	Amendment 047	Kathryn Zoon	Annual Report; General Correspondence - Meeting Request	1
2/3/1998	TCR	From: S. Sickafuse To: J. Gilly	Meeting request	1
2/5/1998	Amendment 048	Kathryn Zoon	Protocol Amendment - New Investigator (CP02-9710, ...)	1
2/5/1998	TCR	From: S. Dayton To: J. Gilly	Conference call to review ... data and strategy	1

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Date	Type	Addressee	Subject	Binder #
2/25/1998	Letter	From: FDA To: J. Gilly	February 19, 198 Letter of Meeting minutes from teleconference discussing sponsor's new Phase 2 protocol (CP02-9710) which studies C225 alone in patients with (amendments 59 and 42)	1
3/2/1998	Amendment 049	Sharon Risso	General Correspondence (Pre-meeting information for virus validation teleconference)	1
3/3/1998	TCR	From: G. Toolan To: S. Sickafuse	Compassionate Use Protocols-France and Japan	1
3/5/1998	Amendment 050	Sharon Risso	General Correspondence (Request for compassionate treatment of a single patient with	1
3/6/1998	Amendment 051	Sharon Risso	Protocol Amendment - Change in Protocol (CP02-9710, Versions 4.0, 4.1, 4.2; ;	1
3/11/1998	TCR	From: J. Gilly, G Toolan To: S. Sickafuse	3-day safety report and compassionate treatment protocol	1
3/12/1998	Amendment 052	Sharon Risso	FDA Request for Information (Response to two questions posed by during review of compassionate treatment protocol).	1
3/12/1998	TCR	From: Dr. B. Parker To: J. Gilly, G. Toolan	Pancreatic Cancer Compassionate Protocol	1
3/13/1998	Amendment 053	Sharon Risso	Initial Safety Report - Mfg. Control #98/02/00070	1
3/13/1998	Amendment 054	Sharon Risso	FDA Request for Information (Revised IC as requested by during 3/12 telephone conversation regarding a single patient treatment protocol)	1
3/18/1998	TCR	From: J. Gilly To: S. Sickafuse	Protocol CP02-9811	1
3/20/1998	TCR	From: S. Sickafuse To: J. Gilly	Protocol CP02-9811	1
4/6/1998	Amendment 055	Sharon Risso	General Correspondence - Meeting Minutes	1
4/17/1998	Amendment 056	Sharon Risso	Protocol Amendment - New Investigator (CP02-9710, ); Information Amendment - Clinical	1
4/30/1998	Amendment 057	Sharon Risso	Initial Safety Reports - Mfg Control #98/002/00071 and #98/02/00072	1
5/11/1998	Letter	From: FDA To: J. Gilly	May 5, 1998 Letter of Meeting minutes from telephone conversation held on March 25, 1998 to review ImClone's current virus validation program and to provide input as to the development of future approaches to virus validation.	1
5/18/1998	Amendment 058	Sharon Risso	Information Amendment - Chemistry (Release Protocol Lot 980077)	1
5/22/1998	Amendment 059	Sharon Risso	Initial Safety Reports - Mfg Control #98/02/00074, #98/02/00076, #98/02/00077	1
6/12/1998	Amendment 060	Sharon Risso	Information Amendment - Clinical (Addendum 1.0 to Version 4.0 of IB); Protocol Amendment - Change in Protocol (CP02-9607, Version 6.0; CP02-9709, Versions 2.0 and 2.1)	1
7/15/1998	Amendment 061	Sharon Risso	Initial Safety Report - Mfg. Control #98/02/00081	1

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7/23/1998	Amendment 062	Sharon Risso	Initial Safety Report - Mfg. Control #98/02/00083, #98/02/00084	1
8/17/1998	Amendment 063	Sharon Risso	Information Amendment - Chemistry (Release protocol Lot 980253); Protocol Amendment - New Investigator CP02-9608; A4 IRB approval for CP02-9710; revised Form FDA 1572 for CP02-9710)	1
9/9/1998	TCR	From: S. Sickafuse To: J. Gilly	IFNa and C225 Combination Protocol	1
9/9/1998	TCR	From: S. Sickafuse To: J. Gilly, G. Toolan	Regulatory Procedure for IFN Trial	1
9/18/1998	Amendment 064	Sharon Risso	FDA Request for Information (PK information); Other - Final Study Report (CP02-9503); General Correspondence - Teleconference Request	1
10/13/1998	TCR	From: G. Toolan To: S. Sickafuse	C225 Phase III Protocols-single meeting request	1
10/15/1998	TCR	From: M. Serabian To: G. Toolan	PK Submission (Serial No. 064)	1
10/16/1998	Amendment 065	Sharon Risso	Initial Safety Report - Mfg. Control #98/02/00095	1
11/2/1998	Amendment 066	Sharon Risso	General Correspondence - Request for Meeting (pre-pivotal trial mtg. C225 + radiation)	1
11/2/1998	TCR	From: Dr. D. Green To: G. Toolan	IND Serial No. 064-PK Information	1
11/3/1998	TCR	From: J. Gilly To: Dr. D. Green	Basis of C225 Dose Selection Question	1
11/4/1998	TCR	From: Dr. D. Green To: J. Gilly, G. Toolan	Review of Interim PK Report	1
11/6/1998	TCR	From: S. Dayton To: J. Gilly	C225 Pre-Phase III meeting-provide alternate dates	1
11/9/1998	Fax	From: S. Dayton To: J. Gilly	Meeting Announcement (confirming 1/7/99 meeting date and time): To receive FDA input on designee of Phase 3 trial	1
11/9/1998	TCR	From: S. Dayton To: J. Gilly	C225 Pre-Phase III meeting-Only date available is January 7, 1999 from 3-4:30pm	1
11/13/1998	Amendment 067	Sharon Risso	Protocol Amendment - Change in Protocol (CP02-9608, Ver. 7.0;	1
12/7/1998	Amendment 068	Sharon Risso	General Correspondence - Meeting Attendees	1
12/11/1998	Amendment 069	Sharon Risso	Information Amendment - Chemistry (Release Protocol Lot 980452)	1
12/21/1998	Amendment 070	Sharon Risso	General Correspondence - Responsible Head Change	1
12/24/1998	Amendment 071	Sharon Risso	General Correspondence - Meeting Attendees	1
1/4/1999	Amendment 072	Sharon Risso	Revision	1
1/4/1999	Amendment 072	Sharon Risso	Annual Report	2
1/5/1999	TCR	From: G. Toolan To: S. Sickafuse	Scheduled meeting of January 7, 1999	2

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			BB-IND 5804 - v	
1/5/1999	TCR	From: P. Keegan, B. Parker To: H. Waksal		2
1/5/1999	TCR	From: B. Parker To: J. Archbold	Call for	2
1/11/1999	TCR	From: S. Sickafuse To: G. Toolan	FDA Request for information	2
1/19/1999	Amendment 073	Sharon Risso	General Correspondence (Request for compassionate treatment of patient with	2
1/19/1999	TCR	From: G. Toolan To: S. Sickafuse	Compassionate protocol	2
1/21/1999	TCR	From: Dr. B. Parker To: G. Toolan	Patient narratives for patients with and single patient compassionate protocol	2
1/21/1999	TCR	From: S. Sickafuse To: G. Toolan	Patient narratives for patients with	2
1/22/1999	Amendment 074	Sharon Risso	General Correspondence (Minutes of Jan 7 meeting)	2
1/26/1999	TCR	From: S. Sickafuse To: G. Toolan	narratives	2
1/27/1999	TCR	From: S. Sickafuse To: G. Toolan	C225 Product Issues	2
1/29/1999	Amendment 075	Sharon Risso	FDA Request for Information (additional information regarding patients with while in a C225 study)	2
2/11/1999	Amendment 076	Sharon Risso	Protocol Amendment – Change in Protocol (CP02-9710, ver 5; ), Protocol Amendment – New Investigator (Change in PI - CP02-9710), Protocol Amendment – New Protocol (CP02-9815, ver 2, ), FDA Request for Information (Response to request for plan to use historical control for C225 alone in studies)	2
2/11/1999	TCR	From: G. Toolan To: S. Sickafuse	CP02-9815, version 2.0	2
2/16/1999	Letter	From: FDA To: H. Waksal	February 10, 1999 Letter of Meeting minutes - January 7, 1999 pre-Phase III meeting with ImClone regarding Chimeric Monoclonal Antibody (C225) to Epidermal Growth Factor Receptor	2
3/1/1999	TCR	From: G. Toolan To: S. Sickafuse	Protocol CP02-9815	2
3/16/1999	TCR	From: B. Shaw To: G. Toolan	Update of projected submission of BLA	2
3/17/1999	TCR	From: G. Toolan To: B. Shaw	Projected date of BLA filing (C225)	2
4/8/1999	Amendment 077	Sharon Risso	General Correspondence – Meeting Request (pre-pivotal trial meeting – ECOG study)	2
4/12/1999	TCR	From: S. Sickafuse To: G. Toolan	FDA Submission Serial No. 077-Request for meeting	2

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4/19/1999	TCR	From: G. Toolan To: S. Sickafuse	Compassionate treatment of patient	2
4/20/1999	Amendment 078	Sharon Risso	General correspondence – Compassionate treatment CP02-9921 (	2
4/21/1999	Amendment 079	Sharon Risso	General Correspondence – Compassionate treatment CP02-9920 (	2
4/21/1999	TCR	From: G. Toolan To: S. Sickafuse	Compassionate treatment-	2
4/23/1999	TCR	From: Dr. B. Parker To: G. Toolan	Compassionate treatment protocols	2
4/23/1999	TCR	From: G. Toolan To: S. Sickafuse	Compassionate treatment protocols	2
4/26/1999	TCR	From: G. Toolan To: Dr. B. Parker	Compassionate Treatment-	2
4/28/1999	TCR	From: G. Toolan To: Dr. B. Parker	Compassionate treatment-	2
4/29/1999	TCR	From: Dr. B. Parker To: G. Toolan	Compassionate Treatment patient	2
5/7/1999	Amendment 080	Sharon Risso	Protocol Amendment – New Investigator (CP02-9815;	2
5/7/1999	Amendment 081	Sharon Risso	General Correspondence – Compassionate treatment CP02-9922	2
5/7/1999	TCR	From: G. Toolan To: S. Sickafuse	Compassionate treatment patient	2
5/13/1999	TCR	From: G. Toolan To: S. Sickafuse	Compassionate treatment-	2
5/13/1999	TCR	From: S. Sickafuse To: J. Archbold	BB-IND 5804	2
5/27/1999	TCR	From: G. Toolan To: S. Sickafuse	Change in PI and site for study CP02-9922	2
6/11/1999	Amendment 082	Sharon Risso	General Correspondence (Responsible Head Designation); Information Amendment – Chemistry (Release Protocol – Lot #990002 [(Finished Goods), 990001=Final Container]); Protocol Amendment – New Investigator (CP02-9922, CP02-9815,	2
6/11/1999	TCR	From: G. Toolan To: S. Sickafuse	Introductions and electronic vs. paper BLA submissions	2
7/8/1999	TCR	From: G. Toolan To: S. Sickafuse	Single patient compassionate treatment-	2
7/12/1999	Amendment 083	Glen Jones	General Correspondence – Compassionate Treatment CP02-9924	2
7/12/1999	Amendment 084	Glen Jones	Protocol Amendment – New Investigator (CP02-9815,	2
7/14/1999	TCR	From: S. Sickafuse To: G. Toolan	Single patient compassionate treatment-	2
8/3/1999	TCR	From: G. Toolan To: M. Fauntleroy	Electronic BLA	2
8/4/1999	E-mail	From: M. Fauntleroy To: G. Toolan	CALA questionnaire	2
8/6/1999	Amendment 085	Glen Jones	General Correspondence - Compassionate Treatment CP02-9927	2

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8/6/1999	TCR	From: K. Winestock To: G. Toolan	Compassionate Treatment	2
8/11/1999	Amendment 086	Glen Jones	Protocol Amendment – New Protocol (CP02-9816, 5397); Protocol Amendment – New Investigator (CP02-9815,	2
8/11/1999	TCR	From: Dr. S. Jerian To: G. Toolan	Compassionate exemption	2
8/12/1999	TCR	From: M. Trapani To: S. Sickafuse	Plans regarding the Cetuximab BLA	2
8/16/1999	TCR	From: G. Toolan To: S. Sickafuse	Adverse Event	2
9/1/1999	Amendment 087	Glen Jones	General Correspondence – Compassionate Treatment CP02-9928	2
9/3/1999	TCR	From: Dr. S. Jerian To: M. Trapani	Compassionate treatment request	2
9/13/1999	Amendment 088	Glen Jones	Other – Meeting Request (Pre-BLA CMC Meeting)	2
9/14/1999	TCR	From: M. Fauntleroy To: G. Toolan	Electronic BLA Guidance	2
9/14/1999	TCR	From: S. Sickafuse To: G. Toolan	Pre-BLA CMC Meeting Request	2
9/17/1999	Amendment 089	Glen Jones	Protocol Amendment – New Investigator (CP02-9709, CP02-9815, E5397, CP02-9816,	2
9/22/1999	Fax	From: S. Sickafuse To: M. Trapani	Meeting Announcement: November 4, 2001 pre-BLA CMC	2
10/1/1999	TCR	From: M. Trapani To: S. Sickafuse	Pre-BLA CMC Meeting Package	2
10/6/1999	Amendment 090	Glen Jones	Information Package – Meeting November 4, 1999 (pre-BLA CMC meeting)	2
10/7/1999	Amendment 091	Glen Jones	Protocol Amendment – New Protocol (CP02-9923,	2
10/13/1999	Amendment 092	Glen Jones	Information Amendment – Chemistry (Release protocol Lot 990261; Comparability protocols, RP0299-01, DP0299-07, DP0299-10; Research report RR0298-15; Research report RR0299-02)	2
10/15/1999	Amendment 093	Glen Jones	Protocol Amendment – New Protocol Compassionate Treatment (CP02-Compassionate, :	2
10/21/1999	Amendment 094	Glen Jones	Initial Safety Report - Mfg. Control #98/02/00118	2
10/22/1999	TCR	From: S. Sickafuse To: G. Toolan	CP02-Compassionate	2
10/25/1999	TCR	From: G. Toolan To: S. Sickafuse	CP02-Compassionate	2
10/27/1999	Amendment 095	Glen Jones	General Correspondence (Compassionate treatment release of product)	2
10/27/1999	TCR	From: S. Sickafuse To: G. Toolan	CP02-Compassionate	2
10/29/1999	Amendment 096	Glen Jones	Protocol Amendment – New Protocol (CP02-9814 ver 2	2

### Cetuximab Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
10/29/1999	TCR	From: S. Sickafuse To: G. Toolan	Pre-BLA CMC Meeting	2
11/1/1999	Amendment 097	Glen Jones	FDA Request for Information (Correspondence to Serial No. 093, Compassionate Treatment Protocol)	2
11/2/1999	Amendment 098	Glen Jones	General Correspondence – Meeting Questions (CMC)	2
11/2/1999	Amendment 099	Glen Jones	Compassionate Treatment – Patient Condition	2
11/5/1999	Amendment 100	Glen Jones	General Correspondence – Meeting Presentation	2
11/10/1999	Letter	From: G. Toolan To: G. Frykman	Desk copy of Version 5.0 of the Cetuximab Investigator's Brochure	2
11/11/1999	Amendment 101	Glen Jones	IND Clinical Hold – Complete Response	2
11/16/1999	TCR	From: M. Trapani To: Dr. Jerian	To discuss the clinical hold on Protocol CP02-Compassionate	2
11/19/1999	Amendment 102	Glen Jones	IND Cross-reference – General Correspondence r	2
11/24/1999	Amendment 103	Glen Jones	Clinical Hold - CP02	2
11/26/1999	Letter	From: FDA To: M. Trapani		2
11/30/1999	TCR	From: M. Trapani To: S. Sickafuse	To confirm whether FDA granted an emergency IND	2
12/1/1999	Amendment 104	Glen Jones	General Correspondence (IND Cross-reference	2
12/1/1999	Amendment 105	Glen Jones	General Correspondence (IND Cross-reference –	2
12/1/1999	Amendment 106	Glen Jones	General Correspondence (IND Cross-reference -	2
12/2/1999	TCR	From: M. Trapani To: B. Friedman	User fee discussion	2
12/20/1999	Letter	From: FDA To: M. Trapani	November 4, 1999 meeting minutes - pre-BLA CMC meeting	2
12/22/1999	Amendment 107	Glen Jones	Protocol Amendment – New Investigator (CP02-9815,	2
12/27/1999	Memo	From: M. Trapani To: All	FDA Meetings Minutes-November 4, 1999 (distributed internally)	2
1/12/2000	Amendment 108	Glen Jones	General Correspondence (Cross Reference letter –	2
1/13/2000	Amendment 109	Glen Jones	General Correspondence (Cross Reference letter –	2
1/13/2000	Amendment 110	Glen Jones	General Correspondence (Cross Reference letter –	2

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Date	Type	Addressee	Subject	Binder #
1/14/2000	Amendment 111	Glen Jones	Response to FDA Request for Information (Virus clearance and validation information)	2
1/25/2000	Amendment 112	Glen Jones	Protocol Amendment – New Protocol (CP02-9813, CP02-9815, Protocol Amendment – New Investigator (CP02-9815, CP02-992, CP02-9816, CP02-9816)	2
2/1/2000	Amendment 113	Glen Jones	Other – CALA Questionnaire	2
2/2/2000	TCR	From: M. Fauntleroy To: G. Toolan	EBLA teleconference and demo	2
2/15/2000	Amendment 114	Glen Jones	Initial safety report (Mfg control # 99/02/00166)	2
2/15/2000	TCR	From: G. Toolan, D. Lynch To: S. Sickafuse	Follow up o Serial No. 111-Final Plan	2
2/15/2000	TCR	From: D. Lynch To: S. Sickafuse	IND Safety Report - Serial No. 114	2
2/18/2000	Amendment 115	Glen Jones	General Correspondence (Cross reference letter –	2
2/22/2000	Amendment 116	Glen Jones	Initial safety report follow up – 7-day (Mfg control # 99/02/00166)	2
2/23/2000	TCR	From: S. Sickafuse To: D. Lynch	Validation Program as submitted as IND Amendment Serial No. 111, 11 January 2000	2
2/24/2000	Amendment 117	Glen Jones	General Correspondence (Cross reference letter –	2
2/25/2000	Amendment 118	Glen Jones	Annual Report	2
2/28/2000	Amendment 119	Glen Jones	Extra copy of annual report	2
2/29/2000	Amendment 120	Glen Jones	General Correspondence (Cross reference letter –	2
2/29/2000	Amendment 121	Glen Jones	General Correspondence (Cross reference letter –	2
3/6/2000	Amendment 122	Glen Jones	General Correspondence (Cross reference letter –	2
3/6/2000	Amendment 123	Glen Jones	Protocol Amendment – Change in Protocol (E5397, Addendum 1; CP02-9923, ver 2); Protocol Amendment – New Investigator (CP02-9814, CP02-9815, CP02-9816, CP02-9817, CP02-9818, CP02-9819, CP02-9820, CP02-9821, CP02-9822, CP02-9823, CP02-9824, CP02-9825, CP02-9826, CP02-9827, CP02-9828, CP02-9829, CP02-9830, CP02-9831, CP02-9832, CP02-9833, CP02-9834, CP02-9835, CP02-9836, CP02-9837, CP02-9838, CP02-9839, CP02-9840, CP02-9841, CP02-9842, CP02-9843, CP02-9844, CP02-9845, CP02-9846, CP02-9847, CP02-9848, CP02-9849, CP02-9850, CP02-9851, CP02-9852, CP02-9853, CP02-9854, CP02-9855, CP02-9856, CP02-9857, CP02-9858, CP02-9859, CP02-9860, CP02-9861, CP02-9862, CP02-9863, CP02-9864, CP02-9865, CP02-9866, CP02-9867, CP02-9868, CP02-9869, CP02-9870, CP02-9871, CP02-9872, CP02-9873, CP02-9874, CP02-9875, CP02-9876, CP02-9877, CP02-9878, CP02-9879, CP02-9880, CP02-9881, CP02-9882, CP02-9883, CP02-9884, CP02-9885, CP02-9886, CP02-9887, CP02-9888, CP02-9889, CP02-9890, CP02-9891, CP02-9892, CP02-9893, CP02-9894, CP02-9895, CP02-9896, CP02-9897, CP02-9898, CP02-9899, CP02-9900, CP02-9901, CP02-9902, CP02-9903, CP02-9904, CP02-9905, CP02-9906, CP02-9907, CP02-9908, CP02-9909, CP02-9910, CP02-9911, CP02-9912, CP02-9913, CP02-9914, CP02-9915, CP02-9916, CP02-9917, CP02-9918, CP02-9919, CP02-9920, CP02-9921, CP02-9922, CP02-9923, CP02-9924, CP02-9925, CP02-9926, CP02-9927, CP02-9928, CP02-9929, CP02-9930, CP02-9931, CP02-9932, CP02-9933, CP02-9934, CP02-9935, CP02-9936, CP02-9937, CP02-9938, CP02-9939, CP02-9940, CP02-9941, CP02-9942, CP02-9943, CP02-9944, CP02-9945, CP02-9946, CP02-9947, CP02-9948, CP02-9949, CP02-9950, CP02-9951, CP02-9952, CP02-9953, CP02-9954, CP02-9955, CP02-9956, CP02-9957, CP02-9958, CP02-9959, CP02-9960, CP02-9961, CP02-9962, CP02-9963, CP02-9964, CP02-9965, CP02-9966, CP02-9967, CP02-9968, CP02-9969, CP02-9970, CP02-9971, CP02-9972, CP02-9973, CP02-9974, CP02-9975, CP02-9976, CP02-9977, CP02-9978, CP02-9979, CP02-9980, CP02-9981, CP02-9982, CP02-9983, CP02-9984, CP02-9985, CP02-9986, CP02-9987, CP02-9988, CP02-9989, CP02-9990, CP02-9991, CP02-9992, CP02-9993, CP02-9994, CP02-9995, CP02-9996, CP02-9997, CP02-9998, CP02-9999, CP02-10000)	2
3/8/2000	Amendment 124	Glen Jones	Response to FDA Request for Information	2
3/10/2000	Amendment 125	Glen Jones	Response to FDA Request for Information (Withdrawal of CP02-Compassionate)	2
3/10/2000	TCR	From: Dr. Jerian To: M. Trapani	Follow-up discussion on the use of Protocol CP02-Compassionate	2
3/10/2000	TCR	From: S. Jerian To: M. Trapani	To determine the use of Protocol CP02-Compassionate	2
3/14/2000	TCR	From: S. Sickafuse To: G. Toolan	Compassionate protocol teleconference	2

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Date	Type	Addressee	Subject	Binder #
3/15/2000	Amendment 126	Glen Jones	Initial Safety Report (Mfg control # 00/02/00193)	2
3/15/2000	Amendment 127	Glen Jones	Information Amendment – CMC (Release Protocol, Lot 990388 [(Finished Goods), 990387=Final Container] Lot 990609; Stability Reports SR0086-01, SR0101, SR0111)	2
3/15/2000	Amendment 128	Glen Jones	General Correspondence (Cross reference letter	2
3/16/2000	Letter	From: G. Toolan for M. Trapani To: S. Sickafuse	Draft Protocol for Compassionate Treatment Teleconference - via Fax	2
3/21/2000	Amendment 129	Glen Jones	General correspondence (Cross reference letter – DAKO)	2
3/21/2000	Memo		ODAC Meeting Minutes	2
3/22/2000	Amendment 130	Glen Jones	IND Safety report – 7 day follow-up (Mfg. Control # 00/02/00193)	2
3/24/2000	Amendment 131	Glen Jones	IND Safety report –15 day (Mfg. Control #00/02/00200)	2
3/24/2000	Amendment 132	Glen Jones	Protocol Amendment – New Investigator (CP02-9815, CP02-9816, CP02-9923, Other (Cross reference,	2
3/24/2000	TCR	From: S. Sickafuse To: D. Lynch	To arrange for a teleconference to discuss ImClone's Cetuximab Program	2
3/31/2000	Letter from FDA	To: M. Trapani From: Glen Jones	Withdrawal of protocol,	2
4/4/2000	Amendment 133	Glen Jones	Other - eBLA demo	2
4/7/2000	TCR	From: S. Sickafuse To: D. Lynch	To request resubmission of the ECOG Clinical Protocol (E5379) contained in the March 6, 2000 (Serial No. 123) IND Amendment and follow-up to our request for a teleconference to discuss the viral validation program	2
4/13/2000	TCR	From: S. Sickafuse To: D. Lynch	Arrange for teleconference to discuss Cetuximab program	2
4/17/2000	Letter	From: D. Lynch To: S. Sickafuse	Notification of availability of ImClone representatives to discuss the Cetuximab Viral Validation plan. - Via Fax	2
4/18/2000	TCR	From: D. Lynch To: S. Sickafuse	Arrange for teleconference to discuss Cetuximab program	2
4/19/2000	Letter	From: FDA To: Manufacturers of Biological Products	Notification to be cautious not to use materials that may be contaminated with BSE and to take measures to ensure that any materials used in production, that have been received from countries where BSE exists, do not contain BSE	2
4/21/2000	Fax	From: D. Lynch To: S. Sickafuse	Telephone conference information; date, time, phone # to call and participant code	2
4/21/2000	TCR	From: D. Lynch To: Dr. Jerian	To arrange for a teleconference regarding the Compassionate Use Program	2
4/24/2000	TCR	From: D. Lynch To: Dr. Jerian	Teleconference to discuss Compassionate Use Program and Cetuximab Development	2

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Date	Type	Addressee	Subject	Binder #
4/27/2000	Amendment 134	Glen Jones	Information Amendment – CMC (Release Protocol, Lot 990764, Lot 990819; Stability Reports SR0059-04, SR0060-04, SR0062-03, SR0072-03, SR0101-01, SR0109)	2
4/28/2000	Amendment 135	Glen Jones	General Correspondence (Cross reference letter –	2
5/1/2000	Amendment 136	Glen Jones	Protocol Amendment – Change in Protocol (E5397, Addendum 1); Protocol Amendment – New Investigator (CP02-9815, E5397, CP02-9816, CP02-9923,	2
5/4/2000	Fax	From: D. Lynch To: Dr. C. Fuchs	List of ImClone representatives who participated in the 5/4/00 teleconference regarding the Cetuximab viral validation program	2
5/4/2000	TCR	From: D. Lynch To: Drs. Fuchs and Webber	Teleconference to discuss the Cetuximab Program	2
5/5/2000	Amendment 137	Glen Jones	Response to FDA Request for Information (Copies of all current protocols & summary of all protocol amendments)	2
5/11/2000	Amendment 138	Glen Jones	Protocol Amendment – New Protocol (CP02-0035, version 1)	2
5/23/2000	TCR	From: P. Delaney To: J. Falcey	ImClone's 800 number (Call Center)	2
5/24/2000	Amendment 139	Glen Jones	Safety Report – Second Follow up (Mfg Control #99/02/00166)	2
5/24/2000	Amendment 140	Glen Jones	General Correspondence (Record of Contact – April 24, 2000 Compassionate Use Protocol)	2
5/31/2000	TCR	From: Dr. Jerian To: G. Toolan	Compassionate protocol CP02-0035	2
6/1/2000	Amendment 141	Glen Jones	Protocol Amendment – New Investigator (E5397, CP02-9816, CP02-9923,	2
6/1/2000	Amendment 142	Glen Jones	General Correspondence (Cross reference letter –	2
6/7/2000	TCR	From: G. Toolan To: S. Sickafuse	Clinical Strategy Meeting-Days of week to request	2
6/9/2000	TCR	From: Dr. Jerian To: G. Toolan	Clarification of lung cancer experience	2
6/13/2000	Amendment 143	Glen Jones	Other-Meeting Request (Clinical Strategy)	2
6/13/2000	TCR	From: D. Lynch To: Dr. J. Meisler	Investigation of shipment error of June 9, 2000 Orphan Drug Submission	2
6/13/2000	TCR	From: D. Lynch To: K. Robertson	Investigation of shipment error of June 9, 2000 Orphan Drug Submission	2

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Date	Type	Addressee	Subject	Binder #
6/14/2000	TCR	From: D. Lynch To: K. Robertson	Investigation of shipment error of June 9, 2000 Orphan Drug Submission	2
6/15/2000	Letter	From: M. Trapani To: M. Haffner	Extension to the 90 day response timeframe defined in your letter of March 20, 2000 for our Orphan-Drug Designation Request for Cetuximab (application #00-1330)	2
6/15/2000	TCR	From: D. Lynch To: Dr. J. Bona	Call was to alert the Office of Orphan Drugs that ImClone will be requesting an extension for the Response to the March 20, 2000 letter	2
6/16/2000	TCR	From: G. Toolan To: D. Ellsworth	Notification of construction of commercial facility	2
6/19/2000	TCR	From: S. Sickafuse To: G. Toolan	Clinical strategy meeting briefing book	2
6/27/2000	Fax	From: E. McFadden To: G. Toolan	Meeting Announcement: 8/11/00	2
6/27/2000	TCR	From: M. Trapani To: K. Souter	Request for FDA meeting-facility	2
6/28/2000	Amendment 144	Glen Jones	Initial 7 Day IND Safety Report (Mfg Control #00/02/00316)	2
6/28/2000	TCR	From: M. Trapani To: S. Sickafuse	Fax regarding SAE	2
6/29/2000	Amendment 145	Glen Jones	Initial 15 Day IND Safety Report (Mfg. Control #00/02/00312)	2
6/29/2000	Amendment 146	Glen Jones	Initial 15 Day IND Safety Report (Mfg. Control #00/02/00301)	2
6/29/2000	Amendment 147	Glen Jones	Initial 15 Day IND Safety Report (Mfg. Control #00/02/00302)	2
6/30/2000	Amendment 148	Glen Jones	Follow-Up to 7 Day IND Safety Report (Mfg. Control #00/02/00316)	2
6/30/2000	TCR	From: M. Trapani To: R. Abrahams	Request for FDA meeting-facility	2
7/3/2000	Letter	From: M. Haffner To: D. Lynch	Letter announcing that cetuximab qualified for orphan designation for the treatment of :	2
7/10/2000	Letter	From: M. Trapani To: D. Ellsworth	Proposal of meeting dates for the discussion of the design of the manufacturing facility	2
7/11/2000	Amendment 149	Glen Jones	Other - Meeting Package (clinical strategy meeting)	2
7/11/2000	Amendment 150	Glen Jones	Initial 7 Day IND Safety Report (Mfg. Control #00/02/00324)	2
7/11/2000	TCR	From: G. Toolan To: S. Sickafuse	Single patient exemption-CP02-0035	2
7/12/2000	TCR	From: M. Needle To: Dr. Jerian	Patient exemption for Compassionate Use	2
7/12/2000	TCR	From: S. Sickafuse To: G. Toolan	-Compassionate Use	2
7/13/2000	Amendment 151	Glen Jones	Safety Report-Follow-up (Mfg. Control Nos. 00/02/00301, 00/02/00302, 00/02/00324)	2
7/13/2000	Amendment 152	Glen Jones	Single Patient Exemption Request	2

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7/13/2000	TCR	From: G. Toolan To: S. Sickafuse	Compassionate Use	2
7/14/2000	TCR	From: G. Toolan To: S. Sickafuse	Single patient exemption-CP02-0035	2
7/17/2000	Amendment 153	Glen Jones	Pre-clinical Safety Report (Mfg. Control #PC 00/02/001)	2
7/18/2000	Amendment 154	Glen Jones	Information Amendment-CMC (Release Protocol Lot No. 000007 & Stability Report SR-0073-04)	2
7/24/2000	Amendment 155	Glen Jones	Initial IND Safety Report-15 Day (Mfg. Control No. 00/02/00334)	2
7/24/2000	TCR	From: Dr. S. Jerian To: D. Lynch	message Re: IND Safety database Review	2
7/26/2000	TCR	From: Dr. S. Jerian To: D. Lynch	Clarification of FDA Request regarding the IND Safety Database Review.	2
7/27/2000	TCR	From: Dr. Serabian To: D. Lynch	Additional information for Assessment of BB-IND 5804 Serial No. 153-Review	2
7/31/2000	Amendment 156	Glen Jones	Response to FDA Request for Information (IB and immunohistochemistry reports)	2
7/31/2000	TCR	From: G. Toolan To: Dr. Serabian	Fax regarding tissue cross-reactivity reports and Investigational Brochure	2
8/2/2000	TCR	From: CA Cartier To: P. Chao	Clarification of export of clinical material.	2
8/3/2000	Amendment 157	Glen Jones	Other: Meeting Attendees	2
8/3/2000	Amendment 158	Glen Jones	Pre-clinical Safety Report Follow-up (Mfg. Control #PC 00/02/0001)	2
8/3/2000	Amendment 159	Glen Jones	Response to FDA Request for Information (Information requested by <u>Dr. S. Jerian</u> 7/27/00)	2
8/4/2000	Amendment 160	Glen Jones	Response to FDA Request for Information (Bleeding events requested by <u>Dr. S. Jerian</u> )	2
8/4/2000	TCR	From: G. Toolan To: Dr. M. Serabian	Follow-up of July-telephone call	2
8/4/2000	TCR	From: G. Toolan To: S. Sickafuse	Call to S. Sickafuse re: information requested to be placed on <u>Dr. M. Serabian</u> desk (sent via fax); verified 8/11 meeting place and request for 5-10 additional set-up minutes	2
8/7/2000	Amendment 161	Glen Jones	IND Safety Report (Mfg. Control #00/02/00349)	2
8/7/2000	TCR	From: M. Trapani To: S. Sickafuse	FDA Contact-August 11 meeting	2
8/8/2000	Memo	From: CA. Cartier To: Reg., Sales, Marketing, Corp. Comm., H. Waksal		2
8/9/2000	TCR	From: D. Lynch To: Dr. M. Lessing	Call was to alert the Office of Orphan Drugs that ImClone will be requesting an additional extension for the Response to the March 20, 2000 letter	2
8/11/2000	Memo	From: D. Lynch To: Reg. File	ImClone's record of the August 11, 2000 meeting with the FDA	2
8/14/2000	Amendment 162	Glen Jones	IND Safety Report follow-up (Mfg. 00/02/00349)	2
8/14/2000	TCR	From: Drs. Serabian/Jerian To: G. Toolan	Follow-up information on the <u>IND Safety Report</u>	2
8/18/2000	Amendment 163	Glen Jones	Information Amendment-CMC (Facility Renovations)	2

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Date	Type	Addressee	Subject	Binder #
8/18/2000	TCR	From: D. Lynch, G. Toolan To: Dr. S. Jerian	Clarification of request for safety data	2
8/21/2000	TCR	From: D. Lynch To: Dr. S. Jerian	Confirm conference call for August 25, 2000 at 9:00am to discuss Independent Review Charter.	2
8/21/2000	TCR	From: Dr. Serabian To: G. Toolan	Conversation with FDA-Monkey studies	2
8/22/2000	Amendment 164	Glen Jones	Protocol Amendment-New Protocol (CP02-9816C ver 1.0); Change in Protocol (CP02-9709, ver 3.0; CP02-9813, ver 2.0; CP02-9814, ver 3.0; CP02-0035, ver 1.1; CP02-9816, ver 4.0); New Investigator (E5397, CP02-9816, CP02-0035, Other – Authorized contact	2
8/25/2000	TCR	From: JF, DL, MN, GT To: SJ, GM	August 25, 2000 teleconference meeting minutes	2
8/29/2000	TCR	From: CA Cartier To: W. Purvis	To inquire about the CBER process for requesting acceptance of proposed proprietary names.	2
8/31/2000	TCR	From: CA Cartier To: Dr. K. Webber	To inquire about the CBER process for brand name selection.	2
8/31/2000	TCR	From: D. Lynch, J. Tarnowski To: Dr. C. Fuchs	To request clarification on "raw data" to be included in validation and characterization reports submitted to the IND and BLA.	2
9/5/2000	Amendment 165	Glen Jones	IND Safety Report (Mfg. Control # 00/02/00385)	2
9/7/2000	Amendment 166	Glen Jones	General Correspondence-Meeting Minutes (August 11, 2000 Clinical Discussion)	2
9/7/2000	Amendment 167	Glen Jones	Request for evaluation & acceptance of proposed proprietary names	2
9/7/2000	Letter	From: M. Trapani To: W. Purvis	Request for evaluation & acceptance of proposed proprietary names - DESK COPY	2
9/8/2000	Amendment 168	Glen Jones	Information Amendment - CMC (Release Protocol Lot 00C00453)	2
9/11/2000	Amendment 169	Glen Jones	General Correspondence-Minutes (August 25, 2000 Teleconference)	2
9/14/2000	Amendment 170	Glen Jones	IND Safety Report-Initial (Mfg Control #PC00/02/002; 00/02/00389)	2
9/19/2000	Amendment 171	Glen Jones	IND Safety Report 7-Day Follow-up (Mfg. Control No. 00/02/00316 (2))	2
9/21/2000	TCR	From: CA. Cartier To: D. Ellsworth, T. Emler	To inquire about available dates for a meeting to discuss the new manufacturing facility.	2
9/28/2000	Letter	From: S. Sickafuse To: M. Trapani	September 22, 2000 Letter of Meeting minutes from August 11, 2000 meeting	2
9/28/2000	TCR	From: S. Sickafuse To: D. Lynch	To inquire as to the number of electronic copies FDA requires for submission	2
9/29/2000	Amendment 172	Glen Jones	Clinical Information – Safety (Narratives Gr. 3&4 allergic reactions, bleeding events, deaths)	2
10/6/2000	Amendment 173	Glen Jones	IND Safety Report Follow-up (Mfg Control #PC00/02/002 (2))	2
10/13/2000	TCR	From: D. Lynch To: M. Fauntleroy	To discuss the formatting requirements for the electronic version of Serial No. 172	2

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Date	Type	Addressee	Subject	Binder #
10/17/2000	TCR	From: CA Cartier To: W. Purvis	To inquire about the status of Cetuximab proposed brand name review.	2
10/20/2000	TCR	From: CA Cartier To: C. Fuchs	To request clarification on Release Protocol data submitted at Serial No. 168	2
10/27/2000	Amendment 174	Glen Jones	Protocol Amendment - New Investigator (CP02-9815, CP02-9816, CP02-9816C, E539, CP02-0035)	2
11/2/2000	Amendment 175	Glen Jones	Clinical Information - Safety (Resubmission of narratives)	2
11/2/2000	Amendment 176	Glen Jones	Clinical Information-HACA Assay (SOP CSOP0014, Protocol CP0013, Report CR0013)	2
11/6/2000	Amendment 177	Glen Jones	IND Safety Report-Initial (Mfg Control #00/02/00457)	2
11/13/2000	TCR	From: M. Trapani To: B. Goldman	To inquire whether references were necessary for Fast Track Designation request	2
11/14/2000	Amendment 178	Glen Jones	Request for Fast Track Designation	2
11/14/2000	Amendment 185	Glen Jones	IND Safety Report Follow-up (Mfg Control #00/02/00457)	2
11/15/2000	Amendment 179	Glen Jones	Information Amendment -- Chemistry (Molecular characterization of DNA Sequencing)	2
11/15/2000	Amendment 180	Glen Jones	Information Amendment -- Chemistry (Purification process description, new process testing, viral validation report and protocol)	2
11/15/2000	Amendment 181	Glen Jones	Information Amendment -- Chemistry (Cell culture process and testing)	2
11/15/2000	Amendment 182	Glen Jones	Information Amendment -- Chemistry (Viral Validation)	2
11/15/2000	Amendment 183	Glen Jones	Information Amendment -- Chemistr	2
11/16/2000	Amendment 186	Glen Jones	General Correspondence-Change in Regulatory Contact	2
11/17/2000	Amendment 184	Glen Jones	Pre-BLA CMC Mtg. Request	2
11/17/2000	Amendment 187	Glen Jones	IND Safety Report Follow-up (Mfg. Control #PC 00/02/002 (2))	2
11/20/2000	TCR	From: D. Lynch, N. Mehta To: C. Fuchs	To provide w/update on (1) moving forward with BLA; (2) demonstrating comparability of drug substance produced at and (3) IND Amendments No. 179 to 184	2
11/21/2000	Amendment 188	Glen Jones	Information Amendment -- Chemistry (Confirmation of successful outcome of clinical study CP02-9923)	2
11/22/2000	Fax	From: N. Mehta To: S. Sickafuse	BB IND 5804 for Cetuximab and our submissions 184 and 188 requesting a pre-BLA meeting.	2
11/22/2000	Fax Alert	From: D. Lynch To: S. Sickafuse	Animal Death (#PC00/02/003)	2
11/29/2000	TCR	From: CA Cartier To: W. Purvis	To inquire about the rationale for the APLS review results and recommendation of Cetuximab proposed brand names	2
11/30/2000	Amendment 189	Glen Jones	IND Safety Report-(Mfg. Control #PC00/02/0030(1))	2

### Cetuximab Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
12/4/2000	Amendment 190	Glen Jones	IND Safety Report-15 Day Report-(Mfg. Control #00/02/00454)	2
12/5/2000	Fax	From: S. Sickafuse To: N. Mehta	Pre-BLA meeting announcement-1/18/01	2
12/7/2000	Memo	From: N. Mehta To: DB, RC, MB, AD, EH, MB, GN, JT, HW, DL	Pre-BLA Meeting announcement-1/18/01	
12/11/2000	Fax Alert	From: D. Lynch To: S. Sickafuse	Animal Death (#PC00/02/004)	2
12/12/2000	Amendment 191	Glen Jones	General Correspondence (Cross reference - )	2
12/13/2000	Amendment 192	Glen Jones	Annual Report	2
12/15/2000	Amendment 193	Glen Jones	Information Amendment -- Chemistry (Amended Background document for CMC meeting)	2
12/15/2000	Amendment 194	Glen Jones	Protocol Amendment - New Protocol (CP02-9932, ver 1.0,	2
12/18/2000	Amendment 195	Glen Jones	IND Safety Report (Mfg. Control #PC00/02/0004)	2
12/18/2000	TCR	From: D. Lynch To: Dr. S. Jerian	Discuss ImClone's plan to study Cetuximab in the treatment IMC CP02-9932	2
12/20/2000	Amendment 196	Glen Jones	Protocol Amendment - New Protocol (CP02-0036, ver 1.0; CP02-9925, ver 1.0)	2
12/20/2000	TCR	From: D. Lynch To: S. Sickafuse	To arrange for a teleconference to discuss Cetuximab program.	2
12/21/2000	TCR	From: D. Lynch To: Dr. C. Fuchs	To arrange for a teleconference to discuss the Cetuximab comparability program for the material product at	2
12/22/2000	TCR	From: S. Sickafuse To: D. Lynch	To request ImClone provide 2 additional copies of Serial No. 193.	2
12/26/2000	Fax Alert	From: D. Lynch To: S. Sickafuse	Animal Death (#PC00/02/005)	2
1/3/2001	TCR	From: M. Serabian To: C. Cartier	To ask questions and discuss comments on the December 13, 2000 Annual Report/IB (Submission Serial No. 192).	3
1/4/2001	Amendment 197	Glen Jones	IND Safety Report (Mfg. Control #PC00/02/005)	3
1/8/2001	TCR	From: Dr. S. Jerian To: D. Lynch	Arrange for a discussion of ImClone's three proposed lung protocols (CP02-9923, CP02-9925, CP02-0036) on January 10, 2001	3
1/8/2001	TCR*	From: S. Sickafuse To: L. Lee	Dates and time for the requested Erbitux FDA meeting	1- BLA
1/8/2001	TCR*	From: S. Sickafuse To: N. Mehta	Regarding our request for a meeting to discuss the issues raised in the December 28 Letter	1- BLA
1/9/2001	Fax	To: K. Webber From: N. Mehta	ImClone participants at teleconference	3
1/10/2001	TCR	From: D. Lynch To: Dr. S. Jerian	To discuss FDA comments on ImClone's three proposed lung protocols (CP02-9923, CP02-9925, CP02-0036)	3
1/11/2001	Amendment 198	Glen Jones	General Correspondence (Cross reference letter -	3
1/11/2001	Letter from FDA	M. Trapani Frd'd to N. Mehta	January 3, 2001 Letter regarding Orphan Drug Application #00-1330	3

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Date	Type	Addressee	Subject	Binder #
1/11/2001	TCR	From: G. Toolan To: S. Sickafuse	Clinical pre-BLA meeting and brand names review.	3
1/12/2001	Fax	From: D. Lynch To: C. Fuchs	Draft Minutes of the January 9, 2001 teleconference regarding drug substance comparability	3
1/12/2001	TCR	From: D. Lynch To: Dr. C. Fuchs	To inform of ImClone's plans to provide for FDA review draft meeting minutes of the January 9, 2001 teleconference regarding drug substance comparability.	3
1/16/2001	Amendment 199	Glen Jones	Information Amendment-Clinical (pre-BLA meeting request)	3
1/17/2001	Amendment 200	Glen Jones	IND Safety Report (Mfg. Control #01/02/00522)	3
1/18/2001	Letter from FDA	Nikhil Mehta	January 12, 2001 Letter regarding Fast Track Designation	3
1/19/2001	Letter from FDA	Nikhil Mehta	Re: Questions 1-6; further information needed to meet criteria for Fast-track designation	3
1/22/2001	Amendment 201	Glen Jones	Protocol Amendment-New Investigator (CP02-9815, E5397, CP02-9b, CP02-9814, CP02-9816C, Other - Authorized Contact	3
1/22/2001	Fax	From: N. Mehta To: S. Sickafuse	Request for telecon to clarify and discuss items listed in the letter dated 1/19/01.	3
1/23/2001	Amendment 202	Glen Jones	Information Amendment-Toxicology (Amendment 2 to 39-week monkey study)	3
1/24/2001	Fax	From: G. Toolan To: M. Serabian	Faxed Dose calculations used for the toxicity protocol 070-087	3
1/24/2001	TCR	From: G. Toolan, N. Mehta To: M. Serabian	Dose conversion calculations-Human to primate	3
1/25/2001	Fax	From: G. Toolan To: S. Sickafuse	Question proposed by the clinical reviewer	3
1/25/2001	E-Mail	From: M. Serabian To: G. Toolan	Dose Extrapolation	3
1/25/2001	Fax	From: N. Mehta To: S. Sickafuse	January 26, 2001 teleconference dial-in information and ImClone representatives	3
1/26/2001	TCR	To: E. McFadden From: D. Lynch	Scheduling of the pre-BLA Clinical/Pre-clinical meeting for Cetuximab BLA	3
1/30/2001	Amendment 203	Glen Jones	IND Safety Report (Mfg. Control #PC00/02/005(1))	3
1/30/2001	Fax	From: E. McFadden To: N. Mehta	Meeting Announcement-pre-BLA Clinical/Pre-clinical	3
1/31/2001	Amendment 204	Glen Jones	Protocol Amendment- New Protocol (CP02-0037, ver1.0; CP02-0038, ver 1.0; CP02-0141, ver 1.0)	3
1/31/2001	TCR	From: D. Lynch To: S. Jerian	Discuss ImClone's approach to submission of the IND Safety Report Follow-up [PC00/02/005(1)] (CLE 0070-087).	3

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Date	Type	Addressee	Subject	Binder #
2/1/2001	Amendment 205	Glen Jones	General Correspondence-Meeting Minutes (1/9/01 telecon and meeting minutes from 1/18/01 Pre-BLA CMC meeting)	3
2/2/2001	Amendment 206	Glen Jones	Information Amendment-CMC (Authorization)	3
2/2/2001	Amendment 207	Glen Jones	Response to FDA Request for Information	3
2/2/2001	TCR	From: CA. Cartier To: S. Sickafuse	To inquire about the review status of brand names for Cetuximab	3
2/6/2001	Amendment 208	Glen Jones	Response to FDA Request for Information (Response to Question 1-Letter from FDA 1/19/01)	3
2/6/2001	Amendment 209	Glen Jones	General Correspondence (1/26/01 Meeting Minutes from 1/10/01 telecon to discuss clinical issues)	3
2/6/2001	Amendment 210	Glen Jones	Response to FDA Request for Information (ASCO abstract)	3
2/6/2001	Letter	From: N. Mehta To: Internal Affairs Staff (HFY-50)	Export Authorization Request	3
2/7/2001	Amendment 211	Glen Jones	Response to FDA Request for Information (SAP, independent response committee charter and CRFs)	3
2/7/2001	TCR	From: D. Lynch To: S. Sickafuse	clarify the procedures to obtain FDA/ImClone meeting minutes	3
2/9/2001	Fax	From: D. Lynch To: C. Fuchs	Proposed table for the presentation of the information requested by CBER for the key Cetuximab lots used in the in vivo preclinical evaluations and clinical studies.	3
2/9/2001	TCR	From: D. Lynch To: Dr. C. Fuchs	cetuximab lots used in in vivo preclinical evaluations and clinical studies.	3
2/9/2001	TCR	From: S. Jerian To: D. Lynch	of the other disciplines (clinical and to ensure the content and format of the table meet the needs of the review team.	3
2/9/2001	TCR	From: S. Jerian To: D. Lynch	To inquire if the Compassionate Use Protocol was open for enrollment	3
2/12/2001	TCR	From: D. Lynch To: S. Jerian	To discuss the Compassionate Use Protocol	3
2/15/2001	TCR	From: C. Fuchs To: D. Lynch	proposed presentation of the information requested by CBER reviewers (CMC, clinical, pharm/tox) for the key Cetuximab lots used in the in vivo preclinical evaluations and clinical studies.	3
2/20/2001	FDA letter	From: FDA To: N. Mehta	1/18/01 meeting minutes	3
2/20/2001	TCR	From: M. Fauntleroy To: CA. Cartier	To notify FDA regarding submission of the e-BLA Demo (Version 2.0) and to inquire if extra desk copies are needed.	3
2/21/2001	Amendment 212	Glen Jones	Other - eBLA Demo 2.0	3

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Date	Type	Addressee	Subject	Binder #
2/22/2001	Amendment 213	Glen Jones	Information Amendment – Clinical (Pre-BLA Clinical background document)	3
2/23/2001	Amendment 214	Glen Jones	Information amendment-Pharmacology/Toxicology (Cross reactivity study GRA00406)	3
2/23/2001	Fax	From: N. Mehta To: S. Sickafuse	Informing FDA we are sending 3 additional copies of the Background document	3
2/26/2001	Amendment 215	Glen Jones	IND Safety Report (Mfg. Control #01/02/00555Tumor Necrosis-EMR study)	3
2/28/2001	Amendment 216	Glen Jones	Information Amendment- Chemistry (Release Protocol Lot 00A00661, Lot 00C00660, [(Finished Goods), 00C00659=Final Container], Lot 00C00963 [(Finished Goods), 00C00962=Final Container])	3
3/5/2001	E-Mail	From: M. Serabian To: N. Mehta	Potential Teleconference Times	3
3/6/2001	Amendment 217	Glen Jones	Response to FDA Request for Information- Pharmacology/Toxicology (Interim report of 39-week study)	3
3/6/2001	Fax	From: G. Toolan To: M. Serabian	Interim summary report for the ImClone/Merck KGaA 39 week monkey study	3
3/7/2001	TCR	From: G. Toolan To: K. Cressotti	Export Authorization Request	3
3/7/2001	TCR	From: G. Toolan To: S. Sickafuse	Export Authorization Request	3
3/8/2001	TCR	From: G. Toolan To: K. Cressotti	Export Authorization Request	3
3/9/2001	Amendment 218	Glen Jones	Response to Request for Information (Pre-clinical lot data)	3
3/9/2001	Amendment 219	Glen Jones	Response to FDA Request for Information (Response to irinotecan in patients who progress on irinotecan)	3
3/9/2001	Amendment 220	Glen Jones	Information Amendment –Pharmacology/Toxicology (Serology report ARFC0294-11)	3
3/12/2001	Amendment 221	Glen Jones	Protocol Amendment - Change in Protocol (CP02-9816 version 5.0; CP02-0038, ver 2.0); New Investigator (CP02-9815, E5397, CP02-9816, P02-9816C, CP02-0038, )	3
3/12/2001	Fax	From: G. Toolan To: M. Limoli	The names and addresses of the consignees (Export Authorization request)	3
3/16/2001	Amendment 222	Glen Jones	Response to FDA Request for Information (Percent of patients receiving C225 by process designation; table of pts. By clinical study, drug sub., Drug prod. and Ref. Mat.)	3
3/19/2001	Amendment 223	Glen Jones	Response to FDA Request for Information (EGFr positivity - Q4 and Q5 for letter dated 1/19/01)	3
3/20/2001	Amendment 224	Glen Jones	Information Amendment – Chemistry updated specification, CoA Lot 6259 and 00C00819)	3
3/21/2001	Fax	From: N. Mehta To: S. Jerian	Body of submission serial no. 223	3

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Date	Type	Addressee	Subject	Binder #
3/22/2001	Amendment 225	Glen Jones	IND Safety Report (Mfg Control #01/02/00555(1))	3
3/25/2001	Fax	From: N. Mehta To: Dr. C. Fuchs	A copy of submission no. 223 (EGFr test kit; filed 5/19/01)	3
3/26/2001	Amendment 226	Glen Jones	Response to FDA Request for Information (additional in vivo results in a refractory tumor setting – xenograft models)	3
3/26/2001	Fax	From D. Lynch To: N. Mehta	Fax forwarded at Twinbrook Conference regarding agenda for March 27, 2001 meeting	3
3/26/2001	Fax	From: D. Lynch To: S. Jerian	Copy of IND Amendment - Serial No. 226	3
3/30/2001	TCR	From: D. Lynch To: S. Jerian	To request patient with Cetuximab under a physician sponsored single patient IND.	3
3/30/2001	TCR	From: G. Toolan To: C. Fuchs	Export Authorization Request	3
4/3/2001	Amendment 227	Glen Jones	Protocol Amendment – Change in Protocol (CP02-9925, ver 2.0; CP02-9932, ver 2.0; CP02-0036, ver 2.0); Protocol Amendment – New Investigator (CP02-9815, E5397, CP02-9925, CP02-0036, CP02-0038, CP02-0141,	3
4/4/2001	Amendment 228	Glen Jones	Information Amendment – CMC (CoAs for Lonza drug product Lot 00C01177=Final Container, 01C01178=Finished Goods; corrected CoA for drug substance Lot 00A01125)	3
4/5/2001	Amendment 229	Glen Jones	General Correspondence – Meeting Minutes (March 27, 2001 pre-BLA meeting minutes)	3
4/10/2001	TCR	From: N. Mehta To: B. Goldman	To discuss plans for Rolling BLA	3
4/10/2001	TCR	From: N. Mehta To: Dr. K. Stein	To inquire about completion of review of the report	3
4/11/2001	Amendment 230	Glen Jones	Response to FDA Request for Information ( et al. manuscript)	3
4/13/2001	Amendment 231	Glen Jones	General Correspondence – Meeting Minutes (April 4, 2001 teleconference); Other – Draft "Dear Doctor" Letter	3
4/16/2001	TCR	From: Dr. C. Fuchs To: N. Mehta	Comment on report	3
4/17/2001	Amendment 232	Glen Jones	General Correspondence – Meeting Minutes (eBLA teleconference)	3
4/17/2001	Fax	From: N. Mehta To: B. Friedman	Request for waiver of User Fees	3
4/20/2001	E-Mail	From: CA Cartier To: M. Fauntleroy	Attached please find the minutes from the April 6, 2001 ImClone/FDA teleconference, per your request	3
4/23/2001	Amendment 233	Glen Jones	Request for submission of portions of BLA	3
4/23/2001	TCR	From: Dr. S. Jerian To: N. Mehta	BLA and Dear Dr. letter	3
4/27/2001	Letter	From: S. Sickafuse To: N. Mehta	Meeting Minutes from 3/27/2001 - pre-BLA clinical meeting	3

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Date	Type	Addressee	Subject	Binder #
5/1/2001	Amendment 234	Glen Jones	Protocol Amendment-New Investigator: CP02-9815 - CP02-9816C - CP02-0035 - CP02-0141 - CP02-0036 -	3
5/1/2001	Amendment 235	Glen Jones	IND Safety Report-New onset, seizure/convulsion; Mfg. Control No. 01/02/00625	3
5/2/2001	Amendment 236	Glen Jones	General Correspondence: Change in Regulatory Contact	3
5/2/2001	Amendment 237	Glen Jones	Regarding electronic submission of medical imaging data	3
5/3/2001	Amendment 238	Glen Jones	Other: Follow up to telephone conversation of 4/23/01	3
5/3/2001	Amendment 239	Glen Jones	Never submitted discussed in teleconference on 5/21/2001	3
5/8/2001	Fax	From: CA Cartier To: S. Giuliani	List of ImClone representatives who participated in the 5/8/2001 teleconference regarding the Cetuximab rolling BLA submission	3
5/8/2001	TCR	From: L. Lee To: Drs. Jerian, Fuchs, Goldman, Serabian	To gain agreement on the proposed BLA timeline submitted to the FDA on 4/23/01	3
5/9/2001	Amendment 240	Glen Jones	Information Amendment-pharm/tox study 221-014	3
5/10/2001	Amendment 241	Glen Jones	Information Amendment-CMC (release of Lots 01C00095, 01C00006 [(Finished Goods); 01C00005=Final Container], 00C00963 [(Finished Goods), 00C00962=Final Container])	3
5/10/2001	Memo	From: L. Lee To: G. Mills, M. Fautleroy	Minutes of discussion on Imaging Submission	3
5/10/2001	Memo	From: L. Lee To: M. Fautleroy	Electronic BLA	3
5/17/2001	Amendment 242	Glen Jones	Other: revised proposal for the electronic submission of imaging data	3
5/17/2001	TCR	From: D. Lynch To: S. Giuliani	To discuss ImClone's proposal to submit Section 6 of the Cetuximab BLA along with Section 8.	3
5/17/2001	TCR	From: L. Lee To: C. Fuchs	1-to discuss the amendment for the comparability report; 2-to discuss potential scenarios for the timing of the submission for the facilities	3
5/17/2001	TCR	From: L. Lee To: C. Fuchs	To follow up with the protocol amendment regarding	3

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Date	Type	Addressee	Subject	Binder #
5/18/2001	TCR	From: C. Fuchs To: L. Lee	Guidance on timing of facilities submission	3
5/21/2001	TCR	From: D. Lynch To: D. Green, S. Giuliani	To discuss with FDA ImClone's proposal to submit Section 6 and Section 8 of the BLA	3
5/22/2001	Amendment 243	Glen Jones	Other: revised timelines for the submission of the cetuximab rolling BLA under Fast Track drug development	3
5/23/2001	TCR	From: G. Toolan, L. Lee, M. Needle To: S. Jerian	To discuss the preclinical Dear Dr. letter and dose reductions	3
5/30/2001	Fax	From: L. Lee To: S. Jerian	Attached is the revised Dear Dr. letter discussing the preclinical toxicology study and the	3
6/1/2001	TCR	From: D. Lynch To: C. Vincent	To obtain User Fee ID number for Cetuximab BLA	3
6/6/2001	Memo	FDA/ImClone	Re: Meeting with CBER's Electronic Submissions and Information Technology Groups for Demonstration of eBLA Demo 4.0	3
6/7/2001	TCR	From: D. Lynch, G. Toolan To: M. Serabian	To discuss the submission schedule and amendment contents for Section 5 (Pharmacology/Toxicology) of Cetuximab BLA	3
6/11/2001	Fax	From: N. Mehta To: C. Fuchs	CMC Table of Contents for the Cetuximab BLA	3
6/11/2001	Fax	From: G. Toolan To: M. Serabian	Draft Item 5 Table of Contents	3
6/12/2001	Amendment 244	Glen Jones	FDA Request for Information – CFRs for CP02-0141, CP02-0038, CP02-0037	3
6/12/2001	Amendment 245	Glen Jones	Other: Amended timelines for the submission of the cetuximab rolling BLA under Fast Track drug development	3
6/12/2001	Fax	From S. Sickafuse To: L. Lee	Letter regarding Rolling BLA	3
6/12/2001	Letter	From: G. Jones To: L. Lee	Rolling BLA	3
6/12/2001	TCR	From: G. Toolan To: M. Serabian	BLA Item 5: Nonclinical pharmacology and toxicology section	3
6/12/2001	TCR	From: S. Jerian To: L. Lee	Discussion of Trade Names and Coverage of C225 in lay press	3
6/14/2001	Amendment 246	Glen Jones	Amendment to the Request for Evaluation and Acceptance of proprietary names	3
6/14/2001	Fax	From: L. Lee To: S. Jerian	Revised "Dear Dr." letter to expand the discussion in the human experience and the findings in the low and mid-dose groups.	3
6/14/2001	Fax	From: L. Lee To: S. Sickafuse, S. Jerian	Fax copy of Amendment to the Request for Evaluation and Acceptance of proprietary names	3
6/15/2001	Amendment 247	Glen Jones	EBLA demo 4.0	3
6/15/2001	Fax	From: B. Friedman To: N. Mehta	Letter regarding BLA application fee waiver granted	3
6/15/2001	Letter	From: J. Axelrad To: N. Mehta	BLA application fee waiver granted	3

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Date	Type	Addressee	Subject	Binder #
6/20/2001	Amendment 248	Glen Jones	7-day IND Safety Report follow-up [Mfg. Control no. 00/02/00451 (1)]	3
6/20/2001	TCR	From: D. Lynch To: C. Vincent	To confirm the procedures for submission of the User Fee Cover Sheet	3
6/21/2001	TCR	From: D. Lynch To: F. Paul	To inquire as to the hours of operation, location of CBERs DCC and any restrictions relative to delivery of electronic submissions and paper submissions	3
6/21/2001	TCR	From: G. Toolan To: M. Serabian	BLA Item 5: Nonclinical pharmacology and toxicology section	3
6/25/2001	Fax	From: L. Lee To: S. Jerian	Summary of Safety data from pilot study (0038); proposal for inclusion of narratives and CRF's in the BLA	3
6/25/2001	TCR	From: S. Jerian To: L. Lee	Approval of "Dear Doctor" letter, trade name discussion and others	3
6/26/2001	Amendment 249	Glen Jones	Other: Dear Doctor letter (Animal deaths and skin toxicity)	3
6/26/2001	Fax	From: L. Lee To: S. Jerian	SAE for patient #1001 with :	3
6/27/2001	Letter	From: C. Limoli, Int'l. Relations To: N. Mehta	Export Authorization letter - Poland	3
6/27/2001	TCR	From: G. Toolan To: V. Carter	Export Authorization Request-Poland	3
6/27/2001	TCR	From: L. Lee To: Dr. S. Jerian	(1) Review safety data from 038 and discussion of control arm for Phase III study; (2) Inclusion of narratives and CRFs for BLA	3
6/28/2001	BLA Initiation	To: G. Jones From: LL	Initiating the Rolling BLA for cetuximab for refractory colorectal cancer	1- BLA
7/3/2001	Fax	From: N. Mehta To: C. Fuchs	The planned manufacturing schedule for Cetuximab at :	3
7/3/2001	TCR	From: L. Lee To: S. Jerian	Clarification of pre-clinical studies information and discussion of Phase 3 design	3
7/6/2001	Fax	From: L. Lee To: C. Broadnax	Summary results from the 10/10 Trademark Evaluation study conducted for IMC-C225.	3
7/9/2001	TCR	From: L. Lee To: S. Sickafuse	Rolling BLA Timeline and mechanism of submission	3
7/10/2001	TCR	From: N. Mehta To: C. Fuchs	Follow-up to BLA filing General Correspondence :	3
7/11/2001	Amendment 250	Glen Jones		3
7/13/2001	Amendment 251	Glen Jones	Other - Proposal for SAS datasets	3
7/16/2001	TCR	From: C. Fuchs To: N. Mehta	Follow-up to BLA filing	3
7/16/2001	TCR	From: L. Lee To: Brad Glasscock	Rolling BLA timeline and mechanism of submission-Final	3
7/16/2001	TCR	From: L. Lee To: S. Jerian	Change of Medical Reviewer for C225	3
7/18/2001	Letter	From: NM To: G. Jones	Extra desk copies of two section of our rolling BLA for cetuximab; CMC section and Pharm/tox section	1- BLA

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Date	Type	Addressee	Subject	Binder #
7/19/2001	Amendment 252	Glen Jones	Protocol Amendment: Change in Protocol: CP02-9815 ver. 4.0, CP02-9925 ver. 3.0, CP02-9932 ver. 3.0, CP02-0036 ver. 3.0, Protocol Amendment: New Investigator: CP02-9815 -  E5397 -  CP02-0035 - CP02-0141 -	3
7/23/2001	Amendment 253	Glen Jones	Other: General Correspondence: Fax with planned manufacturing schedule for cetuximab	3
7/24/2001	Amendment 254	Glen Jones	Other: Meeting Request-CMC	3
7/24/2001	TCR	From: G. Toolan To: S. Sickafuse	Request for additional copies-IND Serial No. 252	3
7/27/2001	Amendment 255	Glen Jones	Other Information on Follow-up for Pat 1001, Study 0038	3
7/27/2001	Letter	From: L. Lee To: G. Jones	Additional copies of IND amendment 252 as requested by:	3
7/30/2001	TCR	From: L. Lee To: S. Sickafuse	Discussion on the Completion of BLA filing	3
7/31/2001	TCR	From: L. Lee To: L. Pai Scherf	Discussion of the Clinical Section of the BLA	3
7/31/2001	TCR	From: N. Mehta To: C. Fuchs	CMC amendments	3
8/6/2001	TCR	From: N. Mehta To: G. Mills	SAS data for imaging submission	3
8/8/2001	Fax	From: E. McFadden To: N. Mehta	Meeting Announcement: September 6, 2001=Pre-Supplement re: new facility & comparability w/irinotecan	3
8/9/2001	Fax	From: A. Choquette To: S. Sickafuse	Teleconference dial-in information	3
8/10/2001	Fax	From: L. Lee To: L. Pai Scherf	Clinical Section (Item 8) of the BLA	3
8/10/2001	TCR	From: L. Lee To: SS, SJ, GM, LPS, VG	Teleconference to discuss outstanding housekeeping issues fro the clinical area during the transition of Medical Reviewers, and to discuss the proposed Reviewers data base	3
8/13/2001	Amendment 256	Glen Jones	Withdrawal of Protocol #CP02-0037	3
8/13/2001	Letter	From: CBER To: LL	Assigned submission tracking number (strn) BL 125033/0	1- BLA
8/13/2001	Letter	From: G. Jones To: L. Lee	Submission Tracking Number assigned to rolling BLA.	3
8/14/2001	Amendment 257	Glen Jones	IND Safety Report Follow-up Mfg. Control #00/02/00334 (1)	3
8/14/2001	Fax	From: A. Choquette To: S. Sickafuse	List of participants from ImClone Systems Incorporated and P-Net at the teleconference 8/10/01.	3

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Date	Type	Addressee	Subject	Binder #
8/20/2001	Fax	From: N. Mehta To: S. Sickafuse	A paper copy of CMC section of our Rolling BLA for cetuximab (STN 125033/0) is being Fed Ex'd per request.	3
8/20/2001	Fax	To: S. Sickafuse From: NM	Paper copy of CMC section being Fed Ex'd	1- BLA
8/23/2001	Amendment 258	Glen Jones	Background document for pre-SBLA mtg	3
8/23/2001	Amendment 259	Glen Jones	IND Safety Report Mfg # 01/02/00757-	3
8/23/2001	TCR	From: N. Mehta To: C. Fuchs	Discussion of PAI timelines	3
8/28/2001	TCR	From: D. Lynch To: M. D. Green	To update on the organization of the PK information in the BLA.	3
8/31/2001	TCR	From: D. Lynch To: M. D. Green	To propose that the detailed PK Summary in the BLA be incorporated in Section 6 rather than Section 8.	3
9/5/2001	Amendment 260	Glen Jones	Information Amendment – Pharm/Tox (070-087 final study report and BLA Section 5 Toxicology Summary)	3
9/5/2001	Amendment 262	Glen Jones	Information Amendment – Chemistry	3
9/5/2001	TCR	From: D. Lynch To: C. Fuchs	To request assistance in locating information regarding the	3
9/7/2001	Amendment 261	Glen Jones	Information Amendment – Clinical (Safety overview for 1st 12 patients in CP02-0038)	3
9/7/2001	TCR	From: G. Toolan To: M. Serabian	BLA Item 5: Nonclinical pharmacology and toxicology section	3
9/7/2001	TCR	From: N. Mehta To: C. Fuchs	Discussion of Specifications and response to question	3
9/10/2001	Fax	From: N. Mehta To: C. Fuchs		3
9/10/2001	Fax	To: C. Fuchs From: NM		1- BLA
9/13/2001	Amendment 263	Glen Jones	Information Amendment – Clinical (BLA discussion item agreements – FDA Reviewer's Data Base and "clock start" submission)	3
9/13/2001	Fax	From: L. Lee To: L. Pai Scherf	Information amendment submitted to IND 5804 on September 7, 2001 regarding the first twelve patients treated in the Cetuximab pilot safety study (Protocol CP02-0038).	3
9/14/2001	Fax	From: L. Lee To: L. Pai Scherf	Updated safety summary for the first 12 patients in the pilot safety study with the toxicity grade information incorporated.	3
9/18/2001	TCR	From: L. Pai Scherf To: L. Lee	An informal meeting to help orient to the BLA	3
9/20/2001	Amendment 264	Glen Jones	Information Amendment - Chemistry (Certificate of Analysis of Cetuximab Reference Standard, Lot No. 01C00314)	3
9/20/2001	Fax	From: L. Lee To: L. Pai Scherf	Information from IND Submission 223 regarding the	3

### Cetuximab Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
9/24/2001	TCR	From: *D. Lynch To: Marlene (Document Control)	To inquire if BB-IND 5804 Serial No. 264 submission (CMC-Information Amendment providing for the Certificate of Analysis of Cetuximab Reference Standard, Lot No. 01C00314) had been logged into CBERs Document Control	3
9/24/2001	TCR	From: D. Lynch To: S. Sickafuse	To inquire if BB-IND 5804 Serial No. 264 submission (CMC-Information Amendment providing for the Certificate of Analysis of Cetuximab Reference Standard, Lot No. 01C00314) had been forwarded to DARP by CBER Document Control	3
9/28/2001	Amendment 265	Glen Jones	Other: Request for Waiver for Pediatric study requirements	3
10/5/2001	Amendment 266	Glen Jones	Protocol Amendment: New Investigator: CP02-9815 - CP02-9816 - I E5397 - CP02-9925 - CP02-0038 -	3
10/5/2001	Letter	From: S. Sickafuse To: Attendees	September 6, 2001, preSupplement meeting with ImClone regarding Cetuximab; IND 5804	3
10/5/2001	Letter (2nd Submission)	From: L. Lee To: G. Jones	Rolling Submission for BLA	1- BLA
10/9/2001	Fax	From: N. Mehta To: C. Fuchs	Additional details for comp. Eval. For C225 manu. At BBG, information on :	3
10/9/2001	TCR	From: N. Mehta To: C. Fuchs	BLA timing, CBERs inspection schedule, bioburden specs for cetuximab bulk, testing for product stability.	3
10/10/2001	Amendment 267	Glen Jones	Other: Discussion of Phase III Randomized Trial in First Line Metastatic Colorectal Cancer	3
10/10/2001	Fax	From: L. Lee To: L. Pai Scherf	Submission 267 (19 pages) sent Fed Ex	3
10/10/2001	Fax	From: N. Mehta To: C. Fuchs	Manufacturing schedule for upcoming runs at SP Pharmaceuticals	3
10/10/2001	Letter	From: L. Lee To: G. Jones	Hard copies of Clinical Reports for Medical Reviewers	1- BLA
10/10/2001	Letter	From: N. Mehta To: G. Jones	Reviewer Aids: CD ROMs of Reviewer Data Base	1- BLA
10/10/2001	TCR	From: L. Lee To: LPS, SS, JS, KS, CF	Follow-up on the status of Brand Name	3
10/11/2001	TCR	From: D. Lynch To: B. Hood	To confirm the receipt of the 2001 Orphan Drug Annual Report	3
10/11/2001	TCR	From: LPS, SJ, GM To: L. Lee	Post-Marketing Study Requirement	3

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Date	Type	Addressee	Subject	Binder #
10/12/2001	TCR	From: C. Fuchs To: N. Mehta	Bioburden: agreement throughout CBER for further specs at Comparability changes.	3
10/15/2001	Letter	From: L. Lee To: G. Jones	Post-marketing study commitment; Rolling BLA timeline	1- BLA
10/18/2001 - 12/3/2001	TCR	From: LL To: FDA	BLA Review: Running list 10/18-12/3/2001	3
10/19/2001	Fax	From: A. Choquette To: S. Sickafuse	Teleconference information for Phase III protocol on 10/30/01 at 9:45am.	3
10/19/2001	Letter	From: N. Mehta To: G. Jones	A CD as a review aid for the PK reviewer which contains the entire Item 6 and relevant portions of Item 8	1- BLA
10/19/2001	TCR	From: N. Mehta To: S. Sickafuse	Contacted at 11:30am to discuss three items.	3
10/22/2001	Fax	From: A. Choquette To: S. Sickafuse	PK reviewer aid CD-Rom tracking information.	3
10/24/2001	Letter	From: FDA To: L. Lee	Letter granting the name Erbitux as the tradename for cetuximab	3
10/25/2001	Amendment 268	Glen Jones	IND Safety Report Mfg. Control #01/02/00880-Ileus	3
10/25/2001	Fax	From: D. Lynch To: S. Sickafuse	FDA notification of an IND Safety Report for a patient being treated under the ECOG protocol describing an event, Ileus.	3
10/25/2001	Fax	From: N. Mehta To: S. Sickafuse	Attachment: letter sent to the FDA regarding the Rolling BLA timeline and Post-marketing study commitments.	3
10/25/2001	Fax	From: S. Sickafuse To: L. Lee	Brand name letter announcing acceptance of the name "Erbitux"	3
10/25/2001	Fax	From: S. Sickafuse To: L. Lee	Letter regarding post-marketing study, and receipt of a revised proposal for a post-marketing confirmatory study	3
10/25/2001	Fax	From: S. Sickafuse To: LL	Letter from FDA regarding post-marketing study	1- BLA
10/25/2001	Letter	From: CBER To: L. Lee	Comments from the review of September 7 - safety report of the first 12 patients from a pilot study  January 31 - submission of protocol CP02-0037 as post-marketing confirmatory study not acceptable; August 13 - acknowledge withdrawal of protocol CP02-0037	1- BLA
10/25/2001	Letter	From: FDA To: L. Lee	Letter regarding post-marketing study, and receipt of a revised proposal for a post-marketing confirmatory study	3
10/26/2001	Letter	From: LL To: FDA - Information Management Team	Completion of Cetuximab BLA	1- BLA
10/30/2001	Amendment 269	Glen Jones	Revised Proposal for Phase III Post-Marketing Study	3
10/30/2001	Fax	From: NM To: C. Broadnax	Copy of planned press release announcing completion of the BLA filing for C225	1- BLA
10/30/2001	FDA Form	From: FDA To: L. Lee	Form FDA 2656 - stamped and initialed received 10/30/2001	1- BLA

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Date	Type	Addressee	Subject	Binder #
10/30/2001	Letter	From: L. Lee To: G. Jones	Revised proposal for Post-marketing study (CP02-0037 version 2.0)	1- BLA
10/31/2001	TCR	From: S. Sickafuse To: N. Mehta	Notification of BLA completion	3
11/1/2001	Letter	From: FDA To: L. Lee	A request from the National Cancer Institute,	3
11/2/2001	Amendment 270	Glen Jones	Request to clarify meeting minutes for the pre-supplement meeting – September 6, 2001	3
11/2/2001	Fax	From: C Broadnax To: N. Mehta	In reference to ImClone's Oct. 30, 2001 request for advisory review of the Erbitux (Cetuximab) press release that announces the filing of a Biologics License Application for Erbitux.	3
11/2/2001	Fax	From: CBER To: NM	Press release announcing the filing of a Biologics License Application for ERBITUX	1- BLA
11/5/2001	BLA Amend 001	G. Jones	Additional CMC and Clinical information and a copy of a letter detailing the Rolling BLA timelines and Planned Amendments	1- BLA
11/7/2001	Letter	From: CBER To: LL	Letter granting pediatric waiver	1- BLA
11/7/2001	Letter	From: FDA To: L. Lee	In reference to our biologics license application for Cetuximab submitted under Section 351 of the Public Health Service Act – Reference made to our correspondence dated Oct. 5, 2001, requesting a waiver of pediatric studies under 21 CFR 601.27 (c).	3
11/8/2001	TCR	From: C. Broadnax To: N. Mehta	Press release announcing the completion of the BLA filing	3
11/8/2001	TCR*	To: C. Broadnax From: N. Mehta	Press release announcing the completion of the BLA filing	1- BLA
11/9/2001	TCR	From: N Mehta 11/09/01 To: M Fautleroy, B. Glassock, D Offringa 11/16/01 To: M Fautleroy	eBLA for Cetuximab In reference to changes in sections of the eBLA and in reference to ImClone filing an amendment by Nov. 30, 2001.	3
11/13/2001	Amendment 271	Glen Jones	IND Safety Report – 15-Day Report Mfg. Control #01/02/00902	3
11/15/2001	Amendment 272	Glen Jones	General Correspondence – Meeting Minutes - October 30, 2001 teleconference recorded by IMCL	3
11/19/2001	Fax	From: L. Lee To: L Pai Scherf	BLA #125033/0 – request for clarification on Study 9923.	3
11/20/2001	TCR	From: L. Lee To: G. Mills	IRAC's rationale for Final Overall Best Response, and Patient Population	3
11/21/2001	Amendment 273	Glen Jones	IND Safety Report – 15 Day Report Mfg. Control #01/02/00909	3
11/21/2001	Fax	From: AMC for NM To: S. Sickafuse	In reference to IND Safety report: Being sent via mail, and by fax in case of a delay due to the upcoming holiday.	3

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Date	Type	Addressee	Subject	Binder #
11/21/2001	Fax	From: L. Lee To: L. Pai Scherf	BLA #125033/0 – request for clarification on Study 9923.	
11/21/2001	Fax	From: N Mehta To: R Neal, C Fuchs	Information which was requested regarding the preparation of the .	3
11/29/2001	BLA Amend 002	G. Jones	Modified versions of Items 11, 12 and the Statistical folder.	1- BLA
11/29/2001	Fax	From: L. Lee To: L. Pai Scherf	List (chart) of patients who died within 30 days of the last dose of Cetuximab.	3
			CP02-0141 study update, fax to (11/19/01)!	
			(11/26/01) CP02-9923	
12/3/2001	BLA Amend 003	G. Jones		1- BLA
12/3/2001	E-mail	From: L. Lee To: G. Mills	Memo regarding Clarification of Variables and Programs.doc	3
12/4/2001	TCR	From: L. Lee To: LPS, GM	Follow-up review issues - comparator scans and IRAC assessments	3
12/4/2001	Fax	From: L. Lee To: L. Pai Scherf, G. Mills	Clarification of data issues	3
12/4/2001	TCR*	To: G. Mills, L. Pai-Scherf From: LL	Follow-up on Review Issues-Comparator Scans and IRAC Assessment	1- BLA
12/5/2001	TCR	From: L. Lee To: G. Mills, L. Pai-Scherf	Request for consolidation of list of issues resolved and clarification of comparator scans	3
12/5/2001	TCR*	To: G. Mills, L. Pai-Scherf From: LL	Request for Consolidation of List of Issues Resolved, and Clarification of Comparator Scans	1- BLA
12/7/2001	BLA Amend 004	G. Jones	Updates all TOCs and index files in the BLA and BLA Amends	1- BLA
12/12/2001	TCR	From: G. Mills, L. Pai-Scherf To: L. Lee	Communication of issues and expectations from ImClone on BLA	3
12/12/2001	TCR*	From: L. Lee To: G. Mills, L. Pai-Scherf	Communication on Issues and Expectations from ImClone on BLA	1- BLA
12/14/2001	TCR	From: L. Lee, C. Anderson To: G. Mills		3
12/14/2001	TCR*	To: G. Mills From: LL		1- BLA
12/17/2001	Amendment 274	Glen Jones	Protocol Amendment – Change in Protocol (CP02-9932, Ver. 4.0); New Investigator (CP02-9815, CP02-9932,	3

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Date	Type	Addressee	Subject	Binder #
12/18/2001	BLA Amend 005	G. Jones	BLA Amend Materials to comply with several requests from FDA Medical Review Team	1- BLA
12/26/2001	BLA Amend 006	J. Siegel	Request for Meeting and Deferral of Filing Decision Version 1 and Version 2 - Via fax	1- BLA
12/26/2001	Fax	From: L. Lee To: JS, KZ, KS, GJ, PK, GM, LPS, SS (ver 1); KZ, KS, GJ, SS, KW, PK, RS, GM, LPS	Request for Meeting and Deferral of Filing Decision	1- BLA
12/26/2001	TCR*	From: L. Lee To: K. Stein	Inform FDA of the Letter Requesting a Deferral of Filing Decision & Request for Meeting	1- BLA
12/28/2001	Fax	From: S. Sickafuse To: L. Lee	RTF letter	1- BLA
12/28/2001	Fax	From: N. Mehta To: S. Sickafuse/ C. Broadnax	ImClone Press Release CBER communication	1- BLA
1/3/2002	TCR*	To: G. Mills From: LL	Informing FDA of Cancer Letter publication	1- BLA
1/4/2002	TCR*	From: L. Lee To: P. Keegan	Discussion with or	1- BLA
1/7/2002	Amendment 275	Jay Siegel	Request for Meeting to Discuss Issues in December 28, 2001 Refusal-to-File Letter from the FDA	4
1/7/2002	Fax	From: L. Lee To: S. Sickafuse	Agenda for proposed meeting with FDA to discuss the 12/28/2001 RTF letter from FDA	4
1/8/2002	Memo	From: L. Lee To: Regulatory File	Computer printout provided on IRAC assessment	4
1/9/2002	Letter	From: FDA To: L. Lee	December 28, 2001 Letter regarding Refusal to File	1- BLA
1/9/2002	TCR*	From: N. Mehta To: S. Sickafuse	Schedule meeting for February 19 so will be present	1- BLA
1/10/2002	TCR	From: D. Lynch To: S. Sickafuse	To inquire if the Preclinical and Clinical Study Reports being included in the IND Annual Report are required to contain the Data Listing	4
1/16/2002	TCR*	From: L. Lee To: S. Sickafuse	Schedule Formal Meeting	1- BLA
1/17/2002	Amendment 276	From: L. Lee To: J. Siegel	Request for Meeting to Discuss Issues in December 28, 2001 Refusal-to-File Letter from the FDA	4
1/17/2002	Fax	From: L. Lee To: S. Sickafuse	Request for Meeting	
1/17/2002	Fax	From: L. Lee To: S. Sickafuse	Request for Meeting - Filed to IND Amendment 276	4
1/18/2002	TCR*	From: L. Lee To: P. Keegan, K. Stein	Inform FDA of Congressional Inquiry	1- BLA
1/22/2002	Fax	From: E. McFadden To: L. Lee	Meeting Announcement: confirmation - 2/26/02 10:00am - 12:00pm, WOC1, Rm 1	4
1/31/2002	Amendment 277	G. Jones	IND Safety Report - Initial 02/02/00977; 15 Day Follow up 00/02/00389 (1)	4
1/31/2002	Fax	From: D. Lynch To: S. Sickafuse	IND Safety Report Alert - (Serial No. 277)	4

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Date	Type	Addressee	Subject	Binder #
1/31/2002	TCR	From: N. Mehta To: C. Fuchs	Timing of :	4
2/1/2002	Amendment 278	G. Jones	Annual Report	4
2/4/2002	Amendment 279	G. Jones	Protocol Amendment - New Investigator: CP02-9815 CP02-9932	4
2/6/2002	Amendment 280	G. Jones	General Correspondence - Submission of faxes sent to FDA 12/26/2001	4
2/6/2002	Amendment 281	G. Jones	CMC Amendment - Three Lot Analyses Data (Lot No.'s 01C00010, 01C00090 [(Finished Goods); 01C00089=Final Container] 01C00503)	4
2/8/2002	Amendment 282	G. Jones	February 26, 2002 Meeting Briefing Packet	4
2/12/2002	Amendment 283	G. Jones	Protocol Amendment - New Investigator: CP02-9815	4
2/12/2002	Fax	From: L. Lee To: R. Yetter	Return of Fed Ex box inadvertently sent to the Document Control Room	4
2/12/2002	Fax	From: L. Lee To: R. Yetter	Return of Fed Ex box inadvertently sent to the Document Control Room - fax with letter	4
2/13/2002	Amendment 284	G. Jones	Initial 15-day IND Safety Report-Inguinal Abscess (mfg. 02/02/00936); Initial 15-day IND Safety Report- (mfg. 02/02/00996)	4
2/13/2002	Fax	From: L. Lee To: S. Sickafuse	Faxed copy of Amendment 284 - IND Safety Reports (Mfg. 02/02/00936; Mfg. 02/02/00996)	4
2/14/2002	Fax	From: L. Lee To: C. Saffron	IND Amendments	4
2/14/2002	TCR	From: L. Lee To: LP Scherf	Inform of IND Amendments	4
2/15/2002	Amendment 285	G. Jones	7 Day Notification and Initial 15-day IND Safety Report (mfg. 01/02/00946)	4
2/15/2002	Fax	From: L. Lee To: S. Sickafuse	Faxed copy of Amendment 285 - IND Safety Report (Mfg. 01/02/00946)	4
2/15/2002	Fax	From: L. Lee To: C. Saffron	Draft - of IND Amendment	4
2/19/2002	Letter	From: L. Sperry To: J. Little, CBER	Lonza 483 Response	4
2/20/2002	Amendment 286	G. Jones	General Correspondence - Revised questions for the Feb. 26th 2002 Meeting	4
2/21/2002	287	G. Jones	Protocol Amendment - EMR 62 202-007, EMR 62 202-009, EMR 62 202-010	4
2/21/2002	288	G. Jones	IND Safety Report - 01/02/00593	4
2/21/2002	Fax	From: L. Lee To: S. Sickafuse	Requested information by and	4
2/25/2002	Fax	From: L. Lee To: S. Sickafuse	Documents in preparation for 2/26/2002 meeting	4
2/25/2002	Fax	From: L. Lee To: S. Sickafuse	Attachments in preparation for 2/26 meeting	4
2/25/2002	Fax	From: L. Lee To: L.Scherf	get copy from send from Washington, DC	4
2/27/2002	Amendment 289	G. Jones	Protocol for EMR 62 202-009	4
2/27/2002	Amendment 290	G. Jones	Additional pre-meeting information for 2/26/02	4

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Date	Type	Addressee	Subject	Binder #
2/28/2002	Fax	To: R. Cooper From: L. Lee	TCR to regarding: Inform of IND Amendments	4
3/1/2002	Fax	From: CBER To: L. Lee	Regarding protocol	4
3/1/2002	Letter	FDA/ImClone	Teleconference to discuss plans for Independent Review Committee	4
3/5/2002	Amendment 291	G. Jones	IND Safety Report Follow-up -01/02/00946(1)	4
3/8/2002	Amendment 292	G. Jones	General correspondence - Cross Reference Letter for	4
3/8/2002	Amendment 293	G. Jones	IND Safety Report Follow-up [02/02/00977 (1)]	4
3/18/2002	Amendment 294	G. Jones	IND Safety Report Follow-up (02/02/01045)	4
3/18/2002	Amendment 295	G. Jones	Meeting Minutes: February 26, 2002	4
3/19/2002	Letter (Amendment 295)	G. Jones	Additional copies of IND Amendment 295	4
3/22/2002	Amendment 296	G. Jones	IND Safety Report - 15 day initial 02/02/01040 -	4
3/22/2002	Amendment 297	G. Jones	Protocol Amendment: Change in Protocol (CP02-0038, CP02-0141, E5397) Protocol Amendment: New Investigator (CP02-9815 - CP02-9816 - ; CP02-9816C - CP02-9923 - CP02-9608 - CP02-9502 -	4
3/25/2002	TCR	From: N. Mehta To: S. Sickafuse	Clinical Meeting for 4/15/2002	4
4/5/2002	Amendment 298	G. Jones	Request for Clinical Guidance Meeting and Pre-Meeting Package	4
4/8/2002	Amendment 299	G. Jones	IND Safety Report - 15-day Follow-Up Report Mfg. Control # 02/02/01045 (1)	4
4/18/2002	Facsimile	From: S. Sickafuse To: L. Lee	Meeting Announcement: confirmation - 6/4/2002	4
4/23/2002	TCR	From: N. Mehta To: C. Fuchs	Discuss BB36 amendment and 007 supply	4
4/25/2002	Facsimile	From: S. Sickafuse To: L. Lee	Reschedule to 5/28/2002; teleconference originally scheduled for 6/13/2002	4
4/25/2002	TCR	From: L. Scherf To: L. Lee	Inquiry about ImClone's position on the requirement of the Test Dose	4
5/2/2002	Amendment 300	G. Jones	BB36 Comparability	4
5/2/2002	Amendment 301	G. Jones	Initial 15-Day IND Safety Report - (Mfg. 02/02/01093)	4
5/3/2002	TCR	From: L. Lee To: L. Pai-Scherf	Determine FDA Teleconference and Meeting dates; heads up on protocols to be submitted	4
5/6/2002	Amendment 302	G. Jones	Protocol Amendment: New Protocol (CP02-0144)	4
5/6/2002	Amendment 303	G. Jones	Protocol Amendment: New Protocol (CA225005 [BMS])	4
5/9/2002	Amendment 304	G. Jones	IND Safety Report - 15-day Follow-Up Report Mfg. Control # 02/02/01093 (1) -	4
5/9/2002	Letter	From: FDA To: L. Lee	Letter informing us of the Clinical Trials Data Bank available at <a href="http://clinicaltrials.gov">http://clinicaltrials.gov</a> .	4

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Date	Type	Addressee	Subject	Binder #
5/9/2002	Letter (Amendment 302)	G. Jones	Additional copies of IND Amendment 302	4
5/9/2002	TCR	From: LL, NM To: PK, LPS, GM	Increase of Sample Size for 007	4
5/13/2002	Letter (Amendment 303)	G. Jones	Additional copies of IND Amendment 303	4
5/23/2002	Fax	To: S. Sickafuse From: L. Lee	Preparation for the May 28th telecon and June 4 meeting in DC	4
5/24/2002	Fax	To: S. Sickafuse From: L. Lee	Dial-in information for 5/28/2002 teleconference to discuss 1) re-analysis plan for 9923 & 0141, 2) IRC for 007, 9923 & 0141, 3) Study EMR 62 202-007, 4) proposal for AE analysis in the BLA resubmission	4
5/30/2002	Amendment 305	G. Jones	IND Safety Report - 15 Day initial 02/02/01075 -	4
5/30/2002	Amendment 306	G. Jones	Cetuximab IB Version 8.0 - dated May 28, 2002	4
5/30/2002	Fax	To: S. Sickafuse From: D. Lynch	IND Safety Report - 15 Day initial 02/02/01075 -	4
5/30/2002	Fax	To: S. Sickafuse From: L. Lee	Preparation for June 4th FDA meeting	4
6/3/2002	Fax	To: L. Lee From: S. Sickafuse	Agenda for tomorrows meeting (6/4/2002)	4
6/3/2002	Letter (Amendment 306)	G. Jones	3 additional copies of Amendment 306	4
6/3/2002	TCR	From: AM Choquette To: D. Slavin	Request for additional copies of Submission Serial No. 303	4
6/7/2002	Amendment 307	G. Jones	May 28, 2002 Teleconference minutes and Presentation from . . . from 6/4/2002 FDA meeting	4
6/7/2002	Fax	From: L. Lee To: S. Sickafuse	Attendees at the May 28th Teleconference	4
6/10/2002	TCR	From: N. Mehta To: C. Fuchs	Status of IND Amendment for BB36	4
6/11/2002	Amendment 308	G. Jones	15-Day IND Safety Report - Erythema Nodosum - mfg. Control no. 02/02/01120	4
6/19/2002	Amendment 309	G. Jones	Release Protocol for Lot 01C00098	4
6/20/2002	Amendment 310	G. Jones	General Correspondence (SWG - S0205); Cross reference letter for .	4
6/20/2002	Amendment 311	G. Jones	Protocol Amendment: New Investigator (CA225005)	4
6/21/2002	E-Mail	From: L. Lee To: BMS, Merck, IMCL	May 28th teleconference meeting minutes as recorded by ImClone	4
6/28/2002	Amendment 312	G. Jones	Meeting request for Clinical Dev. Plan and Pre-meeting package	4
6/28/2002	TCR	To: D. Lynch From: G. Mills, S. Jerian	FDA called to request ImClone provide the Monitoring Plans for all on-going active clinical trials across all INDs	4

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Date	Type	Addressee	Subject	Binder #
6/28/2002 Amended 7/1/2002	TCR	To: D. Lynch From: G. Mills, S. Jerian	FDA called to request ImClone provide the Monitoring Plans for all on-going active clinical trials across all INDs	4
7/1/2002	TCR	From: N. Mehta To: C. Fuchs	Discuss the status of IND amendment 300 (BB36)	4
7/2/2002	Amendment 313	G. Jones	Response to FDA Request for Information -	4
7/2/2002	Fax	From: N. Mehta To: D. Slavin / S. Sickafuse	Request for Meeting for Clinical Development Plan	4
7/3/2002	Amendment 314	G. Jones	Request for Meeting for Clinical Development Plan	4
7/3/2002	Amendment 315	D. Slavin	Request for Meeting for Clinical Development Plan	4
7/3/2002	Fax	From: N. Mehta To: D. Slavin / S. Sickafuse	Request for Meeting for Clinical Development Plan	4
7/3/2002	Letter	From: S. Sickafuse To: N. Mehta	FDA's Meeting Minutes from 5/28/02 Teleconference	4
7/9/2002	Fax	From: N. Mehta To: C. Fuchs	A comparison of Bioburden Test Methods for Cetuximab Drug Substance	4
7/10/2002	Amendment 316	G. Jones	Response to FDA Request for Information - Monitoring Plans - 007, 005 (BMS), 0141, 0038, 9925, 0036, E5397, 9923, 0144, 9932	4
7/10/2002	Letter	From: S. Sickafuse To: L. Lee	Memo of June 4, 2002 meeting	4
7/12/2002	Fax	From: S. Sickafuse To: L. Lee	Meeting scheduled on 9/17 @ 1pm at the FDA	4
7/15/2002	Amendment 317	G. Jones	General Correspondence: TCR re: use of BB 36 C225 material in clinical studies	4
7/15/2002	TCR	From: C. Fuchs To: N. Mehta	Discuss the status of IND amendment 300 (BB36)	
7/17/2002	Amendment 318	G. Jones	IND Safety Report: 15-day Initial Report (Mfg. Control #02/02/01192);	4
7/24/2002	Amendment 319	G. Jones	Protocol Amendment: New Investigator - CP02-0144 - CA225005 - CP02-9815 -	4
7/26/2002	Amendment 320	G. Jones	Initial IND Safety Report - possible pancreatitis (Mfg. Control #02/02/01193)	4
7/29/2002	Letter	From: S. Sickafuse To: L. Lee	FDA sent letter concerning clinical issues at	4
7/29/2002	TCR	Dr. Lee Pai Scherf & Dr. George Mills	Clarifications on Investigation	4
8/2/2002	Fax	From: L. Lee To: G. Jones	7-day Notification initial (Mfg. Control #02/02/01200)	4
8/5/2002	Amendment 321	G. Jones	Information Amendment - CMC - Revised Drug Product Specification to reflect the introduction of a new method for the detection of endotoxin	4
8/6/2002	TCR	Dr. Lee Pai Scherf & Dr. George Mills	Clarifications on Investigation	4
8/8/2002	Amendment 322	G. Jones	Protocol Amendment: New Investigator (CP02-0144, Additional Information CP02-0144, CP02-9815, CA225005,	4

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Date	Type	Addressee	Subject	Binder #
8/9/2002	Amendment 323	G. Jones	15-day Safety Report - 7 Day Notification (Mfg. Control #02/02/01200) =	4
8/9/2002	Fax	From: L. Lee To: Lee Pai Scherf, George Mills	Mtg. Minutes faxed from 7/26/02 and 8/6/02	4
8/14/2002	Amendment 324	G. Jones	CoA for BB36: Drug Product Lot #02C0001B; CoA for Drug Substance Lot # 01J01563	4
8/15/2002	Amendment 325	G. Jones	Other: Revised and Final IRC Charter and Associated Documents	4
8/16/2002	TCR	From: L. Lee To: G. Mills	Revised and Final IRC Charter	4
8/19/2002	TCR	From: L. Lee To: P. Delaney, T. Poigo	Updates on progress of Expanded Access Program	4
8/20/2002	E-Mail	From: L. Lee To: George Mills	Zip files of the Final IRC Charter and Associated Documents (includes CD Rom of files)	4
8/26/2002	Amendment 326	G. Jones	IND Safety Reports: 15-day Follow-up [Mfg. Control #02/02/01193 (1)]; 15-day Follow-up [Mfg. Control #02/02/01200 (1)]	4
8/30/2002	Amendment 327	G. Jones	Amendment to Pre-Meeting Package for September 17, 2002 meeting with FDA	4
8/30/2002	Fax	From: L. Pai Scherf To: George Mills	Prepared Copy of BB-IND 5804 Serial #327	4
9/4/2002	Amendment 328	G. Jones	Protocol Amendment: New Investigator (CP02-0144;	4
9/5/2002	Amendment 329	G. Jones	IND Safety Report-15-Day Initial Report - (Mfg. Control #11996212, 11999893, 1206564)	4
9/9/2002	Amendment 330	G. Jones	IND Safety Report - 15-Day Follow-up [Mfg. Control #02/02/01193 (2)] Confirmation of final diagnosis:	4
9/17/2002	Facsimile	From: D. Lynch To: S. Sickafuse, L. Scherf	7-Day Notification: Mfg. Control #02/02/01250)	4
9/17/2002	Memo		September 17, 2002 Meeting Attendance List	4
9/17/2002	Memo		September 17, 2002 Meeting Presentation* (ImClone) *An electronic copy can be obtained in X:Group/410/Submissions/BB IND 5804-C225/BB IND 5804 Serial No. 327	4
9/20/2002	Amendment 331	G. Jones	IMCL CP02-0144 CRF	4
9/20/2002	TCR	From: L. Lee To: L. Pai-Scherf	Request for information from FDA on Study CP02-0144	4
9/23/2002	TCR	From: C. Fuchs To: N. Mehta	SAE investigation and PTR lot usage	4
9/24/2002	Amendment 332	G. Jones	New Protocol = CA225004 (Medical Monitor; CA225004, Monitoring Plan vAugust 16, 2002	4
9/24/2002	Fax	From: L. Lee To: L. Pai-Scherf	Discussion on IRC Charter: Dial-in information	4

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Date	Type	Addressee	Subject	Binder #
9/25/2002	Amendment 333	G. Jones	IND Safety Report - 15-Day Initial (Mfg. Control #02/02/01250)	4
9/25/2002	TCR	From: G. Mills, L. Pai-Scherf To: L. Lee	FDA comments on the IRC Charter	4
9/27/2002	Fax	From: L. Lee To: G. Mills, L. Pai-Scherf	List of attendees from the 9/25/02 teleconference pertaining to the IRC Charter	4
10/1/2002	Fax	From: L. Lee To: G. Mills, L. Pai-Scherf	Expanded Access Program (EAP) Outline	4
10/1/2002	Fax	From: L. Lee To: S. Sickafuse, L. Pai-Scherf	Proposed revisions to CA225006 and CA225014	4
10/1/2002	TCR	From: L. Lee To: G. Mills, L. Pai-Scherf	Follow-up on the fax to the IRC amendment	4
10/1/2002	TCR	From: L. Lee To: G. Mills, L. Pai-Scherf	Expanded Access Program(EAP)	4
10/2/2002	Amendment 334	G. Jones	IND Safety Report (02/02/01250) Dear Doctor letter - Safety Report previously submitted 9/25 w/o DDL. **Memo attached dating signature obtained from 9/30/02 for submission of DDL to IND	4
10/2/2002	Amendment 335	G. Jones	Protocol Amendment: New Investigator (CA225004;	4
10/2/2002	Fax	From: L. Lee To: P. Delaney via S. Kazmi	EAP (same fax sent to and on 10/1)	4
10/3/2002	TCR	From: L. Pai-Scherf To: N. Mehta	Feedback on Protocol CP02-0144	4
10/7/2002	TCR	From: L. Pai-Scherf To: N. Mehta	Feedback on Protocol CA225006/014	4
10/9/2002	Amendment 336	G. Jones	SAE Initial 15-Day Report (02/02/01283) with	4
10/9/2002	Fax	From: N. Mehta To: L. Pai-Scherf	List of attendees from the 10/9/02 telcon on feedback from Protocols 006 and 014	4
10/10/2002	Fax	From: L. Pai-Scherf To: L. Lee	Summary of 10/9/02 telcon on Protocols 006 and 014	4
10/11/2002	Amendment 337	G. Jones	IND Safety Report 15 Day IND Safety Report Follow-up Mfg. Control #02/02-1250(1)	4
10/16/2002	Letter	From: S. Sickafuse To: L. Lee	September 17, 2002 - Meeting Minutes (as recorded by FDA)	4
10/18/2002	Amendment 338	G. Jones	Protocol Amendment: New Investigator (0144-	4
10/18/2002	TCR	From: L. Pai-Scherf To: L. Lee	FDA to provide feedback on 0144 CRFs	4
10/23/2002	Amendment 339	G. Jones	General Correspondence: 9/27 fax of 9/25 teleconference attendees, 10/1 fax of EAP outline, 10/1 fax of proposed revisions to 006 and 014	4

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Date	Type	Addressee	Subject	Binder #
10/25/2002	Amendment 340	G. Jones	Request for Special Protocol Assessment: Clinical Studies CA225006 and CA225014	4
10/31/2002	Amendment 342	G. Jones	Other: IRC Charter - Amendment 1	4
10/31/2002	Amendment 341	G. Jones	Protocol Amendment: Change in Protocol (CA225004 and CA225005); Protocol Amendment: New Investigator (CA225004)	4
10/31/2002	Fax	To: G. Mills From: L. Lee	Record of conversation on the IRC Charter	4
11/4/2002	Amendment 343	G. Jones	IND Safety Report - 15 Day IND Safety Report Follow-Up Mfg. Control #02/02/01193(3)	4
11/13/2002	Amendment 344	G. Jones	Protocol Amendment: CP02-0144 Protocol Amendment 01 CP02-0144 Pharmacokinetics Companion Protocol	4
11/21/2002	Amendment 345	G. Jones	Protocol Amendment: New Investigator (CP02-0144-	4
11/22/2002	Amendment 346	G. Jones	Information Amendment - CMC (DP-02C00203, DS-02J00036)	4
11/22/2002	Facsimile	To: L. Pai-Scherf, S. Sickafuse From: L. Lee	7-Day Notification, Mfg. Control Number 02/02/01350-	4
11/27/2002	Amendment 347	G. Jones	IND Safety Report-15-Day Initial Report (Mfg. Control No. 02/02/01350)-	4
12/4/2002	Amendment 348	G. Jones	Protocol Amendment: New Protocol - CA225041 (Expanded Access Program)	4
12/10/2002	Fax - 349 (see below)	S. Sickafuse	Via fax: Amendment to Special Assessment Protocol: CA225006 & CA225014 for Serial #349	4
12/17/2002	Fax	From: L. Lee To: Lee pai Scherf	Attached proposal for addressing FDA's suggestion regarding the EAP	4
12/17/2002	TCR	From: L. Lee To: S. Sickafuse	Special Protocol Assessment for CA225006 and CA225014	4
12/19/2002	Amendment 350	G. Jones	Information Amendment: Chemistry, Manufacturing and Controls - Lot release for cetuximab Drug Product 02C00063 and 02C00292B	4
12/19/2002	Amendment 351	G. Jones	Protocol Amendment: New Investigator (CP02-0144: CA225004:	4
12/20/2002	Fax	To: Dr. J. Schatcher, G. Mills, Ms. Pat Delaney Sickafuse From: L. Lee	ImClone & BMS Proposal to FDA on the EAP	4
12/23/2002	Amendment 352	G. Jones	Information Amendment: Chemistry, Manufacturing and Control	4
12/24/2002	Amendment 349	G. Jones	Amendment to Request for Special Protocol Assessment: Clinical Studies CA225006 and CA225014	4
12/24/2002	Amendment 353	G. Jones	Detailed Statistical Analysis Plan CP02-9923, CP02-0141, EMR 62 202-007	4

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Date	Type	Addressee	Subject	Binder #
12/24/2002	Amendment 354	G. Jones	General Correspondence: December 10, 2002 facsimile December 17, 2002 facsimile December 20, 2002 facsimile	4
1/2/2003	Fax	From: G. Jones To: L. Lee	Fax indicating IND Amendment #340 - Request for Special Protocol Assessment (SPA) for Protocol CA225014 is incomplete as discussed during the 12/6/02 telcon.	5
1/13/2003	Amendment 355	G. Jones	Request: Special Protocol Assessment for: CA225014 (CA225014 v3.0, Monitoring Plan, SAP CA225014, DSMB Charter, Final revised IRC, CRF, Informed Consent	5
1/14/2003	Amendment 356	G. Jones	New Protocol: CA225009 New Protocol: CA225012	5
1/14/2003	Fax	From: L. Lee To: G. Jones	Cover Letter for Serial #355: Special Protocol Assessment for Clinical Protocol CA225014	5
1/15/2003	Amendment 357	G. Jones	Protocol Amendment: New Investigator (CA225041,	5
1/16/2003	Fax	From: L. Lee To: S. Sickafuse	List of attendees from 12/6/02 Teleconference	5
1/23/2003	Amendment 358	G. Jones	General Correspondence: Status Update on Efforts to Address RTF Issues	5
1/23/2003	Fax	From: L. Lee To: S. Sickafuse	Serial No. 358 faxed to	5
1/27/2003	Fax	From: S. Sickafuse To: L. Lee	SPA - not complete and not eligible at this time	5
1/29/2003	TCR	From: S. Sickafuse To: NM, LL	Follow-up to status update on efforts to address RTF issues	5
1/31/2003	Letter	From: G. Jones To: L. Lee	Letter dated 1/24/03 indicating IND Amendment #340 - Request for Special Protocol Assessment (SPA) for Protocol CA225006 is incomplete and not eligible for SPA at this time.	5
1/31/2003	TCR	From: N. Mehta To: G. Mills	SAS Data for Imaging Submission	5
2/3/2003	Amendment 359	G. Jones	Protocol Amendment: New Investigator (CP02-0144: CA225041: CP02-0144 PK Companion:	5
2/3/2003	Fax	From: L. Lee To: G. Mills	Dial-in information for 2/5/2003 telecon and Pre-mtg documentation	5
2/5/2003	Fax	From: L. Lee To: G. Mills	List of attendees from 2/5/2003 teleconference	5
2/6/2003	Amendment 360	G. Jones	(dated 2/5 but not sent via UPS until 2/6) 15-Day IND Safety Report Mfg. Control No. 03/02/01440	5
2/6/2003	Fax	From: D. Lynch To: S. Sickafuse	15-Day IND Safety Report Mfg. Control No. 03/02/01440	5
2/6/2003	Fax	From: L. Lee To: P. Delaney	Copy of press release announcing Expanded Access Program	5
2/6/2003	TCR	From: N. Mehta To: G. Mills	Discussion of the clinical studies: 9923, 0141, 007	5

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Date	Type	Addressee	Subject	Binder #
2/12/2003	Fax	From: L. Lee To: L. Scherf	Request for input on Safety Narratives	5
2/14/2003	Fax	From: L. Lee To: Sharon Sickafuse & Lee Pai Scherf	7-Day Notification received 2/10/2003 follow-up information to the report of submitted on 2/6/2003	5
2/15/2003	TCR	From: L. Lee To: G. Mills, L. Pai-Scherf	Format and requirements for safety narratives	5
2/19/2003	Fax	From: L. Lee To: G. Mills, L. Scherf	Meeting Minutes from 2/14/03 teleconference	5
2/20/2003	E-Mail	From: L. Lee To: G. Mills, L. Pai-Scherf	Regarding ImClone's response to issue of definitions of	5
2/20/2003	Fax	From: L. Lee To: G. Mills, L. Scherf	Point-to-Point response regarding SPA Protocol CA225014	5
2/20/2003	Fax	From: L. Lee To: G. Mills, L. Scherf	Dial-in information for 2/21/03 teleconference on Protocol CA225014	5
2/21/2003	Amendment 361	G. Jones	IND Safety Report Follow-up Mfg. Control No. 03/02/01440 (1)	5
2/21/2003	Amendment 362	G. Jones	Information Amendment: CMC Lot release information Lot No. 02C00062	5
2/21/2003	TCR	L. Scherf	Discussion re: proposal to address FDA's concerns on CA225014 Special Protocol Assessments	5
2/25/2003	Amendment 363	G. Jones	Sent via e-mail on Zip files to be followed up with hard copies on 2/26/03	5
2/25/2003	E-Mail	From: L. Lee To: G. Mills, L. Pai-Scherf	SPA CA225014; zip files containing response to FDA for 014, cover letter for 363, 2/21/2001 TCR, 2/20/2003 fax	5
2/26/2003	Amendment 364	G. Jones	Agreement on format and requirements for safety narratives	5
2/27/2003	E-Mail	From: L. Lee To: G. Mills, L. Pai-Scherf	Dial-in information for 2/27/03 telcon on Minimum duration of prior CPT-11	5
2/27/2003	Fax	From: L. Lee To: G. Mills, L. Pai-Scherf	Dial-in information for 2/27/03 telcon on Minimum duration of prior CPT-11	5
2/28/2003	Amendment 365	G. Jones	Outline of Clinical & Pre-Clinical Rationale for Combination therapy of Cetuximab &	5
2/28/2003	Amendment 366	G. Jones	Status Report on PK Issues -Protocol EMR 62 202-012 -SAP for Integrated PK Analysis	5
2/28/2003	Fax	From: G. Jones To: L. Lee	SPA letter from FDA on Protocol CA225014	5
2/28/2003	Fax	From: L. Lee To: L. Pai-Scherf	Attendees List from 2/27/03 teleconference regarding	5
2/28/2003	TCR	From: L. Lee To: G. Mills, L. Pai-Scherf	FDA's feedback on ImClone's proposal regarding minimum prior	5
3/3/2003	Amendment 367	G. Jones	Status of On-going Studies	5

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Date	Type	Addressee	Subject	Binder #
3/4/2003	Amendment 368	G. Jones	Protocol Amendment: New Investigator (0144- [replaces Anderson], PK 0144- CA225014- CA225041 ; CP02-0144 Monitoring Plan	5
3/10/2003	Amendment 369	G. Jones	Request Special Protocol Assessment for: CA225006 (CA225006 v3.0, Monitoring Plan, SAP CA225006, DSMB Charter, Final revised IRC, CRF, Informed Consent	5
3/10/2003	Fax	G. Jones	BB IND Serial No. 369 Cover Letter Faxed to FDA - Request Special Protocol Assessment for: CA225006	5
3/10/2003	Letter	From: G. Jones To: L. Lee	Request for Special Protocol Assessment to amendment Protocol CA225014	5
3/11/2003	Amendment 370	G. Jones	Information Amendment: CMC (report of investigation of cetuximab drug product lot number 01C00098)	5
3/14/2003	Amendment 371	G. Jones	Protocol Amendment: New Investigator (0144- PK for 0144	5
3/18/2003	TCR	From: L. Lee To: G. Mills, L. Paischerf	Response to ImClone's proposal submitted on March 9 (facsimile) for resolution of definition of minimum	5
3/19/2003	Fax	From: L. Lee To: G. Mills, L. Paischerf	Teleconference Meeting Minutes From 3/18/03	5
3/19/2003	Letter	From: G. Jones To: L. Lee	Letter dated 3/14/2003 regarding Proposal to define adequate exposure CP- 020023, CP-020141 and EMR-007	5
3/20/2003	Amendment 372	G. Jones	Protocol Amendment: New Investigator (0144- updated 1572 for PK for 0144- CA225014- CA225041	5
3/21/2003	Amendment 373	G. Jones	Request for a Clinical Guidance Meeting with the Agency.	5
3/21/2003	Fax	To: S. Sickafuse From: L. Lee	BB IND Serial No. 373 Cover Letter Faxed to FDA - Requesting a Clinical Guidance Meeting with the Agency. (failed attempt on 3/20/2003)	5
3/25/2003	Amendment 374	G. Jones	Information Amendment- Chemistry, Manufacturing, and Controls (lot release for lot no. 02C00292A)	5
3/26/2003	Amendment 375	G. Jones	IND Safety Report- 15-Day Report. Mfg. Control #03/02/01481 ( IND Safety Report - 15-Day Report Mfg. Control #03/02/01484	5
3/26/2003	TCR	From: N. Mehta To: C. Fuchs	Discussion on the status of lot number 01C00098 associated with cluster of AEs	5
3/27/2003	Fax	From: E. McFadden To: L. Lee	Meeting Confirmation: June 5, 2003	5
3/31/2003	Amendment 376	G. Jones	Annual Report (reporting period December 2001 - December 2002)	5

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Date	Type	Addressee	Subject	Binder #
3/31/2003	Amendment 377	G. Jones	General Correspondence: Agreement on Definition of Minimum Prior Irinotecan	5
4/1/2003	Amendment 378	G. Jones	SAP(and Independent Review Committee Carter) CP02-0144	5
4/1/2003	Fax	To: S. Sickafuse & L. Scherf From: L. Lee	Revised List of questions regarding the protocol, protocol design, study conduct, study goals and data analysis	5
4/7/2003	Amendment 379	G. Jones	Investigator Brochure Version 9.0	5
4/7/2003	E-mail	From: L. Lee To: G. Mills, L. Scherf	Dial-in information for telcon held on 4/8/03 on SPA CA225006	5
4/7/2003	TCR	To: Dr. Chan Fuchs From: N. Mehta	Discussion on the status of lot number 01C00098	5
4/8/2003	Fax	From: L. Lee To: G. Mills, L. Scherf	List of attendees from the 4/8/03 telcon on SPA CA225006	5
4/11/2003	Letter	G. Jones	Additional copies of IND amendment 379 as requested	5
4/14/2003	Amendment 380	G. Jones	General Correspondence: Letter of Authorization to FDA for _____, MD	5
4/16/2003	Amendment 381	G. Jones	IND Safety Report - 15 Day Report. Mfg. Control #02/02/01342	5
4/16/2003	TCR	To: Dr. Chan Fuchs From: N. Mehta	Discussion of the status of lot number 01C00098	5
4/17/2003	Amendment 382	G. Jones	Statistical Analysis Plan: EMR 62 202-007, CP02-9923, CP02-0141	5
4/18/2003	Amendment 383	G. Jones	SPA Clinical Protocol C225006	5
4/21/2003	Amendment 384	G. Jones	IND Safety Report - 15 Day Report. Mfg. Control # 03/02/01490 (	5
4/21/2003	Amendment 385	G. Jones	Amendment to Request for Special Protocol Assessment: Revised IRC Charter for CA225006	5
4/21/2003	Fax	G. Jones	Revised section 4.4.5 of Final IRC Charter	5
4/21/2003	Fax	To: S. Sickafuse From: L. Lee	IND Safety Report - 15 Day Report. Mfg. Control # 03/02/01490 (	5
4/23/2003	Amendment 386	G. Jones	IND Safety Report - 15 Day Report. Mfg. Control # 03/02/01499 (	5
4/23/2003	TCR	To: Chana Fuchs From: N. Mehta	Discuss BB36 Process/Comparability Amendment and 007 Supply	5
4/23/2003	TCR	Dr. Lee Pai Scherf	Discuss Status of :	5
4/25/2003	Amendment 387	G. Jones	Revised Protocols: CA225009, CA225012 Protocol Amendment: New Investigator (CA225014-CA225041 CP02-0144- CP02-9932	5
4/29/2003	Amendment 388	G. Jones	General Correspondence - Copy of fax that contained a list of questions regarding CA225006 submitted as IND amendment 385	5
4/29/2003	Letter	To: Dr. Lily Lee From: G. Jones	FDA Responses to list of questions regarding CA225006 submitted as IND amendment 385	5
5/2/2003	Amendment 389	G. Jones	Protocol Amendment: New Investigator (CA225012	5

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Date	Type	Addressee	Subject	Binder #
5/6/2003	Amendment 390	G. Jones	Information Amendment: Chemistry, Manufacturing, and Control Toxin Investigation in Lot 01C00098	5
5/8/2003	Amendment 391	G. Jones	FDA Clinical Guidance Mtg. June 5, 2003 Pre-Meeting Package - Includes: Executive Summary, Addressing the Refusal-to-File Issues, Questions to FDA, Pre-clinical and Clinical Rationale, and Appendices	5
5/9/2003	Amendment 392	G. Jones	Protocol Amendment: New Protocol CA225006 New Investigator CA225006 CA225014 , CA225041 (	5
5/12/2003	Amendment 393	G. Jones	Attachments (tables and figures) for Rationale of Combination Treatment contained in Serial No. 391 (Pre-Meeting Package)	5
5/13/2003	TCR	To: Sharon Sickafuse From: Dr. Lily Lee	Confirm receipt of the June 5th pre-meeting package	5
5/13/2003	Amendment 394	G. Jones	Letter	5
5/14/2003	Amendment 395	G. Jones	March 20, 2003 Meeting Minutes: Demo for Imaging Submission	5
5/16/2003	Amendment 396	G. Jones	Partial Clinical Hold - ImClone's Complete Response to FDA Comments	5
5/22/2003	Amendment 397	G. Jones	IND Safety Report- 15-day Follow-up Report Mfg. Control #03/02/01481(1)	5
5/22/2003	Fax	To: Dr. Martin Green, Sharon Sickafuse From: Dr. Lily Lee	Synopsis of Results for Pharmacokinetics and Pharmacodynamics Studies CA225004 and CA225005	5
5/22/2003	Fax	To: Dr. Patricia Keegan From: Dr. Lily Lee	Time and Location of Erbitux Presentations and Poster Outlines for ASCO 2003	5
5/22/2003	Fax	To: S. Sickafuse & L. Scherf From: L. Lee	IND Safety Report - 7-Day Notification Mfg. Control # 03/02/01497	5
5/22/2003	TCR	To: Dr. Lee Pai Scherf From: Dr. Lily Lee	To discuss Pre-June 5th Meeting Preparation with	5
5/27/2003	Amendment 398	G. Jones	CA225004 and CA225005 Clinical Study Reports	5
5/27/2003	Fax	To: Dr. L. Pai-Scherf, Dr. G. Mills, Dr. M. Green, cc: Sharon Sickafuse From: Dr. Lily Lee	Overview of Content and Structure of the Clinical/Statistical Section Module 5 of CTD	5
5/28/2003	Amendment 399	G. Jones	Copy of Fax Sent 2/27/03 Regarding the Content and Structure of the Clinical/Statistical Section Module 5 of CTD	5
5/29/2003	Amendment 400	G. Jones	IND Safety Report Clarification: Mfg. Control # 03/02/01497 (Change in Investigator Causality Assessment)	5
5/29/2003	Fax	To: Dr. L. Pai-Scherf From: Dr. Lily Lee	List of Investigators, Affiliations, and Number of Patients Enrolled in Each Site and List of Protocol Deviations for EMR-007 Study	5

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Date	Type	Addressee	Subject	Binder #
5/30/2001 & 6/1/03	Summary of Discussions	To: Lee Pai-Scherf and Pat Keegan From: Dr. Lily Lee	Summary of Discussions held at ASCO Regarding Content and Structure of BLA	5
6/5/2003	Fax	To: Dr. L. Pai-Scherf From: Dr. Lily Lee	List of response rates by clinical sites for study EMR-007	5
6/6/2003	Amendment 402	G. Jones	Protocol Amendment (PG): CA225014 Monitoring Plans: CA225004 and CA225005 New Investigator CA225006  CA225014 CA225041	5
6/6/2003	Fax	To: S. Sickafuse From: Dr. Nikhil Mehta	Request for a Pre-BLA CMC Teleconference	5
6/9/2003	Amendment 403	G. Jones	Copy of Fax Which Contains an Overview of the Content and Structure for the Clinical/Statistical Section of Module 5 of the CTD	5
6/9/2003	Amendment 404	G. Jones	IND Safety Report - 15 Day Report Mfg. Control #03/02/01505	5
6/10/2003	Amendment 401	G. Jones	Special Protocol Assessment Modification and Revised IRC Charter for CA225014	5
6/10/2003	Amendment 401- Fax	G. Jones	Duplicate Cover Letter of Serial No. 401- Special Protocol Assessment Modification and Revised IRC Charter for CA225014	5
6/10/2003	Amendment 405	G. Jones	Information Amendment: Chemistry, Manufacturing, and Control - Lot Release Documentation for Lot No. 02C00486	5
6/11/2003	Fax	To: Sharon Sickafuse From: Dr. Lily Lee	Duplicate cover letter of Serial No. 396 (Partial Clinical Hold-Complete Response-1 as requested by the Agency	5
6/12/2003	Fax	To: Dr. Chana Fuchs From: Dr. Lily Lee	Incidence of CA225041(EAP Protocol)	5
6/12/2003	Fax	To: Dr. Lee Pai Scherf From: Dr. Lily Lee	Incidence of CA225041(EAP Protocol)	5
6/13/2003	Email	To: Dr. Lee Pai Scherf From: Dr. Lily Lee	Incidence of CA225041(EAP Protocol)	5
6/16/2003	Amendment 406	G. Jones	Final Clinical Study Report for EMR 62 202-007	5
6/16/2003	Email	To: Dr. Lee Pai Scherf From: Dr. Lily Lee	Information to facilitate arrangement for Clinical Site Audits (CP02-9923, CP02-0141, EMR 62 202-007)	5
6/17/2003	Amendment 407	G. Jones	Information for Clinical Site Audits (CP02-9923, CP02-0141, EMR 62 202-007) and copies of faxes previously sent pertaining to EMR 62 202-007	5
6/19/2003	Amendment 408	G. Jones	Information Amendment- Chemistry, Manufacturing, and Controls (Lot Release Information for Lot No. 02C00673)	5
6/18-6/19/03	TCR	To: Dr. Lee Pai Scherf From: Lily Lee	Comments on the Reviewer's data base	5
6/18/2003	Email	To: Dr. Lee Pai Scherf From: Lily Lee	Proposed structure of reviewer's data base	5

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Date	Type	Addressee	Subject	Binder #
6/20/2003	Letter	G. Jones	FDA Response re Partial Clinical Hold (Clinical Hold Removed)	5
6/20/2003	Fax	To: Sharon Sickafuse From: Dr. Lily Lee	ImClone Minutes and Presentation from June 5, 2003 FDA Meeting	5
6/20/2003	Fax	To: Nik Mehta From: Emily McFadden	FDA Confirmation of Pre-BLA CMC Teleconference - scheduled for July 31, 2003	5
6/20/2003	Email	To: Dr. Lee Pai Scherf From: Lily Lee	007 Zip File, Protocol and Amendment	5
6/24/2003	Amendment 409	G. Jones	Pre-BLA CMC Meeting package	5
6/24/2003	Email	To: Dr. Lee Pai Scherf and Dr. George Mills From: Dr. Lily Lee	Revised document for the reviewers database that includes: an Executive Summary and a Detailed Description of Each Data Set	5
6/24/2003	Email	To: Dr. Lee Pai Scherf and Dr. George Mills From: Dr. Lily Lee	Dial in information for Reviewers Database Teleconference	5
6/24/2003	Letter	To: L. Lee From: FDA	Transfer of IND FDA Review and Oversight from CBER to CDER	5
6/25/2003	Fax	To: Dr. Lee Pai Scherf From: Dr. Lily Lee	Request for Information from EMR-007 for Clinical Site Audit	5
6/25/2003	Email	To: Dr. Lee Pai Scherf From: Lily Lee	BOND Study Report	5
6/27/2003	Amendment 410	G. Jones	New Investigator CA225006  CA225014 CA225041 (Fuloria) Investigator Documentation CA225014 CA22504	5
7/1/2003	Amendment 411	G. Jones	Additional copies of Pre-BLA CMC Pre-Meeting Package (Serial No: 409) as Requested by	5
7/1/2003	Letter	To: L. Lee From: FDA	FDA Memo (minutes) of June 5, 2003 meeting	5
7/8/2003	Amendment 412	G. Jones	e-BLA demo	5
7/11/2003	Amendment 413	G. Jones	General Correspondence: Sponsor's minutes to the June 5, 2003 FDA meeting, (EMR-007), Agreement on Structure of Reviewer's Data Base	5
7/18/2003	Amendment 414	G. Jones	General Correspondence: Documents regarding the observation of CA225041	5
7/18/2003	Amendment 415	G. Jones	General Correspondence: DLT for BLA Test Load	5

### Cetuximab Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
7/28/2003	Amendment 416	G. Jones	- Protocol Amendment: New Investigators CA225006  CA225012 ( ) CA225014 CA225041 CP02-0144 - CA225041 Protocol Amendment 01& 02 - CA225041 Revised Protocol 01	5
7/30/2003	Fax	To: S. Sickafuse From: N. Mehta	Dial in information for CMC Pre-BLA Teleconference and list of attendees	5
7/30/2003	Amendment 417	G. Jones	IND Safety Report- 15-day Follow-up Report Mfg. Control #03/02/01440 (2)  IND Safety Report- 15-day Follow-up Report Mfg. Control #02/02/01093 (2)	5
8/8/2003	Amendment 418	G. Jones	Justification for FDA Image Review Station Hardware Upgrade	6
8/8/2003	Amendment 419	G. Jones	General Correspondence: Cross-Reference Letter Authorization for to use IND for the Compassionate Treatment of	6
8/8/2003	Fax	To: G. Mills From: L. Lee	Proposed schedule for delivery and tutorial for ERBITUX BLA Medical Imaging Review	6
8/8/2003	Fax	To: M. Fauntleroy From: L. Lee	Rationale for Upgrade of Imaging Review System Hardware	6
8/8/2003	Fax	To: G. Mills From: L. Lee	Rationale for Upgrade of Imaging Review System Hardware	6
8/11/2003	Fax	To: G. Mills From: L. Lee	Discussion on Proposal to Upgrade FDA's Imaging and Review System	6
8/11/2003	Fax	To: M. Fauntleroy From: L. Lee	Discussion on Proposal to Upgrade FDA's Imaging and Review System	6
8/11/2003	Letter	To: L. Lee From: Earl Dye for Glen Jones	Response to the June 10, 2003 submission which contained revisions to protocol CA225014 and to the IRAC charter that reflect the comments provided by the FDA in review of clinical protocol CA225006, in which protocol CA225014 was accepted for Special Protocol Assessment.	6
8/14/2003	TCR	To: R. Levin From: L. Lee	Discussion surrounding ImClone's proposal to upgrade FDA's hardware and software for radiology review system	6
8/20/2003	Fax	To: Sharon Sickafuse/Monica Hughes From: N. Mehta	List of Attendees and their titles at the July 31st CMC Pre-BLA Teleconference for cetuximab	6

### Cetuximab Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
8/21/2003	Amendment 420	G. Jones	IND Safety Report- 15-day Follow-up Report Mfg. Control #03/02/01505 (1)  (Update of Amendment 404 -	6
8/26/2003	Amendment 421	G. Jones	New Investigator: CA225006  Revised 1572: CA225041 ( ), CP02-0144	6
8/28/2003	Letter	From: FDA To: L. Lee	Copy of memorandum from July 31, 2003 telephone conversation between ImClone Systems and FDA regarding :	6
9/17/2003	TCR	To: Lily Lee From: Dr. P. Keegan	Request for Investigator IND and review status	6
9/23/2003	Amendment 422	G. Jones	CA225009: Revised protocol No. 02 (dated 5/1/03), Revised protocol No. 03 (dated 5/12/03), and Revised protocol No. 04 (dated 7/8/03) Administrative Letters dated 5/10/03 and 7/8/03, Monitoring Plan, New Investigator: New Investigator: CA225006  Revised 1572: CP02-0144	6
9/24/2003	Amendment 423	G. Jones	General Correspondence: : Reference Letter for Physician Sponsored IND	6
9/24/2003	TCR	To: Dr. Pat Keegan and Lee Pai Scherf From: Lily Lee	Follow-up regarding Investigator INDs and EAP program	6
9/25/2003	Amendment 424	G. Jones	Special Protocol Assessment: CA225014	6
9/25/2003	Amendment 425	G. Jones	Special Protocol Assessment: CA225006 (Study specific questions, Revised protocol, Informed Consent template, Revised IRC Charter 3.0)	6
9/29/2003	Amendment 426	G. Jones	General Correspondence: Reference Letter	6
10/1/2003	Amendment 427	G. Jones	General Correspondence: Reference Letter	6
10/6/2003	TCR	To: George Mills From: Debbie Lynch	Disussion regarding IRC Charters for CA225006 and CA225014	6
10/10/2003	TCR	To: Sharon Sickafuse From: Debbie Lynch	Physician Sponsored IND Applications:	6
10/14/2003	Amendment 429	G. Jones	Protocol Amendment: New Investigator CA225006  CA225012	6
10/15/2003	Amendment 428	G. Jones	IND Safety Report - 15-Day Report Mfg. Control #12394664	6

### Cetuximab Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
10/15/2003	TCR	To: Karen Jones From: Debbie Lynch	Tabular listing of all revisions to clinical protocols CA225006 and CA225014	6
10/15/2003	TCR	To: Lee Pai-Scherf From: D. Lynch and P. Molloy	IND Safety Report for Protocol CA225041	6
10/16/2003	TCR	To: Monica Hughes From: Debbie Lynch	CA225014 Protocol Revision Summary and Physician Sponsored IND Applications	6
10/17/2003	E-mail	To: G. Mills From: L. Lee	Revised IRC Charter Study CA225006	6
10/17/2003	TCR	To: Debbie Lynch From: Mary Andrich	Confirmed receipt of Revised IRC Charter Study CA225006	6
10/21/2003	Amendment 430	G. Jones	IND Safety Report - 15-Day Report Mfg. Control #03/02/01954	6
10/22/2003	TCR	To: Lily Lee From: Dr. U and Jose Tavaréz	Details of the Clinical Site Audit	6
10/23/2003	Amendment 431	G. Jones	General Correspondence:	6
10/23/2003	Fax	To: Lee Pai Scherf From: Debbie Lynch	Identification of Protocol Changes for Studies CA225014 and CA225006	6
10/28/2003	Amendment 432	G. Jones	General Correspondence: Reference Letter	6
10/30/2003	Amendment 433	G. Jones	IND Safety Report - 15-Day Report Mfg. Control #02/02/01051 - Mfg. Control #12394664(1) - follow-up report.	6
10/31/2003	TCR	To: Sharon Sickafuse From: Debbie Lynch	Physician Sponsored IND	6
11/4/2003	Amendment 434	G. Jones	Protocol Amendment: New Protocol CA225020 (E8200) Protocol Amendment: New Investigators CA225020 (E8200):	6
11/4/2003	TCR	To: Lee Pai Scherf & Mark Thornton From: L. Lee	Request for Information: Studies with BB36 material, Pulmonary AEs; Inquiry regarding ODAC	6
11/7/2003	Amendment 435	G. Jones	Protocol Amendment: New Investigators CA225006:  EMR 62 202-025:	6
11/7/2003	Amendment 436	G. Jones	Information Amendment - Chemistry, Manufacturing and Controls (Lot release information for Drug Product Lot 02C01149 and the bulk drug substance Lot No. 02J00265)	6
11/13/2003	Amendment 437	G. Jones	IND Safety Report - 15-Day Follow-up Report Mfg. Control #02/02/01051 - follow-up report	6
11/18/2003	Email	To: Lee Pai Scherf From: L. Lee	Confirmation for Telecon on 11/19/2003	6

### Cetuximab Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
11/19/2003	Email	To: Lee Pai Scherf From: L. Lee	Attendees from 11/19/03 teleconference	6
11/21/2003	Amendment 438	G. Jones	General Correspondence: Reference Letter	6
12/2/2003	Email	To: Lee Pai Scherf From: Lily Lee	Update of Adverse Reaction Section of PI	6
12/2/2003	Email	To: Lee Pai Scherf From: Lily Lee	Update of Adverse Reaction Section of PI - Administrative Information	6
12/2/2003	Email	To: Lily Lee From: Lee Pai Scherf	FDA Attendee List from 12/5/03 Telcon	6
			Protocol Amendment: New Investigators CA225006:  62 202-025:  CA225012: CA225014: CA225020 (E8200): CP02-0036: CP02-0141:	
12/8/2003	Amendment 439	G. Jones	General Correspondence: National Cancer Institute Cross Reference letter	6
12/8/2003	Amendment 440	G. Jones	Protocol Amendment: New Protocol CA225045 Protocol Amendment: New Investigator -	6
12/9/2003	Amendment 441	G. Jones	Protocol Amendment: New Investigator CA225006:  EMR 62 202-025:  CA225020 (E8200): CA225045:	6
12/17/2003	Amendment 442	G. Jones	Information Amendment - Chemistry, Manufacturing and Controls (Lot release information for Drug Product Lot 03C00036 and the bulk drug substance Lot No. 200181)	6
12/17/2003	Amendment 443	G. Jones	FDA Response to Special Protocol CA225014 Revisions submitted	6
12/22/2003	Letter	To: Lily Lee From: Earl Dye	FDA Response to Special Protocol CA225006 Revisions submitted	6
12/22/2003	Letter	To: Lily Lee From: Earl Dye	General Correspondence: Cross Reference Letter	6
12/23/2003	Amendment 444	G. Jones	SPA Modification: Clinical Protocol CA225014 includes revised DSMB Charter, revised IRC Charter and revised protocol 05	6
12/30/2003	Amendment 445	G. Jones	Notification of ImClone Systems' Address Change	6
1/5/2004	Amendment 446	G. Jones		6

### Cetuximab Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
1/9/2004	Amendment 447	G. Jones	Special Protocol Assessment: Protocol CA225006, a list of items being submitted for SPA Review, and questions regarding CA225006 Clinical Protocol and IRC Charter	6
1/12/2004	Amendment 448	G. Jones	Protocol Amendment: New Investigators EMR 62 202-025:  CA22501: CA225020 (E8200): CA22504: CP02-0144:	6
1/20/2004	Amendment 449	Glen Jones	Information Amendment - Chemistry, Manufacturing and Controls Notification of Osmolality and IEF specification changes	6
1/23/2004	E-mail	To: Lee Pai-Scherf From: Lily Lee	Study-014 DSMB Recommendation	6
1/26/2004	Amendment 450	Glen Jones	General Correspondence: Reference Letter	6
1/27/2004	Amendment 451	Glen Jones	Special Protocol Assessment: Protocol CA225014 Data Safety Monitoring Board Results	6
1/29/2004	E-mail	To: Sharon Sickafuse and Lee Pai-Scherf	Study-014 DSMB Package	6
2/3/2004	Amendment 452	Glen Jones	General Correspondence: Cross Reference Letter	6
2/3/2004	Amendment 453	Glen Jones	General Correspondence: Cross Reference Letter for BMS Study CA225059	6
2/9/2004	Amendment 454	Glen Jones	Information Amendment - Chemistry, Manufacturing and Controls (Lot release information for Drug Product Lot No. 03C00516 and the bulk Drug Substance Lot No. 201400)	6
2/10/2004	Amendment 455	Glen Jones	IND Safety Report - 15 Day [Mfg. #04/02/02202 & 04/02/02170]	6
2/10/2004	Amendment 456	Glen Jones	Post Marketing of Adverse Drug (mfr #12495933)	6
2/13/2004	Amendment 457	Glen Jones	Protocol Amendment: New Investigators  : EMR 62 202-025:  : CA225020 (E8200):  CA225041:  : CP02-0144:	6
2/13/2004	Amendment 458	Glen Jones	IND Safety Report - 15 Day Report [Mfg. Control #12497202]	6
2/17/2004	Amendment 459	Glen Jones	General Correspondence: Cross Reference Letter	6

### Cetuximab Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
2/20/2004	Amendment 460	Glen Jones	Protocol Amendment: New Investigators EMR 62 202-025:	6
2/23/2004	Amendment 461	Glen Jones	IND Safety Report - 15 Day Follow-up Report [Mfg. Control #04/02/02202 (1)]	6
2/24/2004	Amendment 462	Glen Jones	General Correspondence: Transfer of Drug Safety Reporting to BMS	6
2/25/2004	Amendment 463	Glen Jones	IND Safety Report - 15 Day Report [Mfg. Control #12494035] IND Safety Report - 15 Day Report [Mfg. Control #12488326] IND Safety Report - 15 Day Report [Mfg. Control #12511564]	6
2/27/2004	Amendment 464	Glen Jones	Protocol Amendment: New Investigators CA225006:  CA225014:	6
2/27/2004	Fax	To: Sharon Sickafuse From: Lily Lee	Request for Meeting: Clinical Guidance Meeting with the FDA Clinical Review Team - 4/12-19/04	6
2/27/2004	Amendment 465	Glen Jones	Request for Meeting: Clinical Guidance Meeting with the FDA Clinical Review Team - 4/12-19/04	6
3/2/2004	Fax	From: Emily McFadden To: Lily Lee	Other IND Proposed Meeting: April 29, 2004, in Rockville, MD, from 14:30 -16:00 EST.	6

### BLA 2003 Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
8/6/2003	Letter	FDA Mellon Client Service Center	Check (#082519) for the BLA in the amount of \$533,400.00	1
8/12/2003	Other	To: Glen Jones From: L. Lee	Installation of the hard drive/monitors and 49 Image DVDs in office	1
8/14/2003	Letter	To: Glen Jones From: L. Lee	Submission of original BLA application with 49 Image DVDs (Archival Copies)	1
8/21/2003	TCR	To: Monica Hughes From: N. Mehta	Status of STN number and Review Team. STN number not yet assigned, but review team formed.	1
8/22/2003	TCR	To: Monica Hughes From: N. Mehta	STN number to be provided at a later date.	1
8/22/2003	TCR	To: George Mills From: N. Mehta	- Installation of the final validated application for the Imaging Review System on 8/26/03 - Email informing and team of upcoming plans as discussed with	1
8/25/2003	TCR	To: Karen Jones From: N. Mehta	BLA STN number assigned - 125084/0	1
8/26/2003	Other	To: George Mills From: N. Mehta	Installation of the Application CD on the hard drive in office. Additionally, the updated information from Image DVDs #5 and #8 were installed on office system.	1
8/26/2003	Amendment 001	To: Glen Jones From: L. Lee	- Amended Labeling TOC with additional hyperlink to WORD version of proposed package Insert. - Amended CRF TOC with correction to the identification of treatment studies on certain studies.	1
8/26/2003	Other	To: George Mills From: N. Mehta	Review Aid to: - 8/25/03 CD containing responses to request for information (Note: These responses will also be filed to the BLA as amendment 002) - 2 copies of the Bioluming BJB Manual containing User Manual (8/22/03) and IRC Documentation (8/25/03)	1
9/2/2003	Email	To: Sharon Sickafuse From: N. Mehta	Verification that the correct versions of the Amendment 001 TOCs (Labeling and CRF) have been loaded.	1
9/2/2003	Letter	To: L. Lee From: Earl Dye for G. Jones	Official letter stating FDA receipt of BLA, FDA Submission Tracking Number, and intent to review the application for accelerated approval	1
9/3/2003	Amendment 002	To: Glen Jones From: L. Lee	Corrected Labeling TOC	1
9/4/2003	Letter	To: George Mills From: Debbie Lynch	Copy of Reviewers Aid CD and inventory sheet sent per request to his home address	1
9/4/2003	TCR	To: Chana Fuchs From: N.Mehta, L.Lee	Manufacturing Facility Inspections	1
9/5/2003	TCR	To: Sharon Sickafuse From: N. Mehta	Multiple discussions with regarding Amendments 001 and 002.	1

### BLA 2003 Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
9/9/2003	Amendment 003	To: Glen Jones From: L. Lee	- Response to the requests by: Registration Number - Archival copy of the Medical Imaging Review System Application CD installed in office on August 26, 2003. - Dako cross-reference letter	1
9/9/2003	TCR	To: L. Lee From: Debbie Trout	Inspection of Manufacturing Facilities 1. Nov. 5 to 14, 2003 2. Dec. 1-5, 2003 3. Still under discussion	1
9/10/2003	TCR	To: Sharon Sickafuse From: L. Lee	Additional Information regarding	1
9/10/2003	Letter	To: Rosa Brown From: L. Lee	Registration of as manufacturer of clinical supplies and as manufacturer of cetuximab.	1
9/11/2003	TCR	To: Chana Fuchs From: N. Mehta	BLA information and Inspection of Manufacturing Facilities	1
9/11/2003	TCR	To: Jose Tavarez From: L. Lee	Clinical Site Audit for BLA	1
9/12/2003	TCR	To: Jose Tavarez From: L. Lee	Information regarding clinical site audits	1
9/12/2003	TCR	To: S. Sickafuse From: L. Lee	Request for database information	1
9/12/2003	Fax	To: L. Lee From: Jose Tavarez	The following sites have been selected for inspection for BLA STN 125084, ERBITUX: - Study 007:  - Study 9923:  - Notebooks with additional information will be required.	1
9/15/2003	Fax	To: Jose Tavarez From: L. Lee	Response to 9/12/03 fax re: Clinical Site Audit for BLA. Names and contact information for European sites selected for inspection.	1
9/15/2003	Fax	To: Gerry McGirl From: L. Lee	Names and contact information for European sites selected for inspection.	1
9/15/2003	TCR	To: Jose Tavarez and Gerry McGirl From: L. Lee and D. Lynch	Scheduling of Clinical Site Audits	1
9/16/2003	Fax	To: George Mills From: L. Lee	Information requested to identify data variables and databases	1
9/17/2003	Fax	To: Jose Tavarez From: L. Lee	Response to 9/12/03 fax re: Clinical Site Audit for BLA. Names and contact information for CP02-0141 and CP02-9923 sites selected for inspection.	1
9/17/2003	TCR	To: Lily Lee From: Pat Keegan	Request for Investigator IND and review status	1
9/17/2003	Fax	To: Gerry McGirl From: L. Lee	Response to 9/12/03 fax re: Clinical Site Audit for BLA. Names and contact information for CP02-0141 and CP02-9923 sites selected for inspection.	1

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Date	Type	Addressee	Subject	Binder #
9/17/2003	TCR	To: Gerry McGirl From: L. Lee	007 Audit schedule and Site Notebook information	1
9/19/2003	Amendment 004	To: G. Jones From: L. Lee	120-Day Safety Update including Safety Summary/tables/listings for Study IMCL CP02-0144	1
9/19/2003	Email	To: Gerry McGirl From: L. Lee	Inspections/Audits BLA STN 125084	1
9/22/2003	Fax	From: L. Lee To: Gerry McGirl	Hotel Recommendations and Local Authority Addresses	1
9/23/2003	TCR	From: Debbie Lynch To: Jose Tavaréz	Confirmed that Clinical Site Notebooks for US sites would be delivered to FDA on September 26, 2003. Also confirmed address to be delivered.	1
9/24/2003	Fax	From: L. Lee To: Jose Tavaréz	Hotel Recommendations and Local Authority Addresses	1
9/24/2003	Fax	To: L. Lee From: Jose Tavaréz	Information requested in teleconference including additional data needed for foreign sites selected for inspection	1
9/25/2003	Fax	To: Jose Tavaréz From: L. Lee	Overall Contact information for Clinical Site Audits for Study EMR 62 202-007 (Dr. Thomas Wenzel)	1
9/25/2003	Letter	To: Jose Tavaréz From: L. Lee	Clinical Site Audit Notebooks for: CP02-0141 ?) CP02-9923 060,	1
9/26/2003	TCR	To: Debbie Trout From: N. Mehta	Limited inspection to: Follow-up the 2001 inspection and to inspect new lots. Also, Cardinal Inspection team formed	1
9/30/2003	TCR	To: Gerry McGirl From: Debbie Lynch	Clinical Site Notebooks: Confirmed that electronic copies would not be needed and the notebooks were to be shipped directly to FDA inspectors	1
9/30/2003	TCR	To: Jose Tavaréz From: Debbie Lynch	confirmed receipt of U.S. Site Notebooks sent 9/25/03. provided that the European Site Notebooks would be sent directly to the FDA investigators the 1st week in October.	1
9/30/2003	Fax	To: Jose Tavaréz From: L. Lee	Letters from each of the EMR 62 202-007 principal investigators authorizing the site inspection by FDA and allowing for access to the patient records. Also included was a letter from ImClone confirming that FDA will have access to the patient records.	1
10/1/2003	TCR	To: Sharon Sickafuse From: L. Lee	Carton and vial label and status of BLA review	1
10/1/2003	TCR	To: Debbie Trout From: L. Lee	Proposal for an earlier inspection at	1
10/2/2003	Letter	To: Sandra Shire From: L. Lee	EMR 62-202 007 Clinical Site Notebooks as requested in the September 12 fax from.	1
10/2/2003	Letter	To: Gerald McGirl From: L. Lee	EMR 62-202 007 Clinical Site Notebooks as requested in the September 12 fax from	1

## BLA 2003 Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
10/2/2003	Letter	To: Dr. Khin U From: L. Lee	EMR 62-202 007 Clinical Site Notebooks as requested in the September 12 fax from	1
10/9/2003	Amendment 005	To: G. Jones From: L. Lee	1. Identification of the EMR 62-202-007 variables in the database 2. Revised vial and carton label providing lot number and expiration date	1
10/9/2003	TCR	To: S. Sickafuse From: N. Mehta	Status of BLA Review regarding "Acceptable for filing" letter, ODAC decision, and DAKO's filing	1
10/10/2003	Fax	To: L. Lee From: Earl Dye	Fax informing ImClone that FDA has filed BLA and that the user fee goal date is February 13, 2004.	1
10/15/2003	TCR	To: Debbie Trout From: N. Mehta	Status of BLA Review	1
10/17/2003	TCR	To: Gerry McGirl From: Debbie Lynch	Finalized travel plans for upcoming clinical site inspections for EMR 62 202-007.	1
10/20/2003	Letter	To: Lily Lee From: Earl Dye	Letter informing ImClone that FDA has filed BLA and that the user fee goal date is February 13, 2004.	1
10/21/2003	E-mail	To: Gerry McGirl From: Lily Lee	Inspections/Audits BLA STN 125084	1
10/22/2003	TCR	To: Chana Fuchs From: N. Mehta	Preparation for Inspection of Cetuximab Manufacturing Facilities	1
10/22/2003	TCR	To: Jose Tavaréz, Dr. U From: L. Lee	Details of Clinical Site Audit	1
10/23/2003	TCR	To: Dr. U and Dr. Lee Pai Scherf From: Lily Lee	Question on randomization scheme for 007 and test dose	1
10/23/2003	Fax	To: J. Tavaréz, Dr. U From: L. Lee	BOND Study Report explaining the method of assigning patients to treatment groups.	1
10/24/2003	Fax	To: L. Lee From: S. Sickafuse	Potential Review Issues ("Day 74 Letter")	1
10/28/2003	TCR	To: Sharon Sickafuse From: L. Lee	Clarification of "Day 74 Letter"	1
10/28/2003	TCR	To: Debbie Trout From: N. Mehta	BB36 Inspection	1
10/28 & 10/31	TCR	To: Chana Fuchs From: N. Mehta	Lots manufactured at	1
10/29 and 10/30	TCR	To: Lily Lee From: Lee Pai Scherf	Request for clarifications on HACA data variables	1
10/30/2003	Fax	To: L. Lee From: S. Sickafuse	Potential Review Issues (Replaces previous "Day 74 letter" )	1
10/30/2003	Fax	To: Lee Pai Scherf From: L. Lee	Reponse to Request for clarifications in the HACA data set	1
10/31/2003	Fax	To: Chana Fuchs From: N. Mehta	Requested information tables for lots which have been manufactured since the last inspection	1
10/31/2003	Email	To: Chana Fuchs and Debbie Trout From: N.Mehta	Requested BB36 plant policy, manufacturing schedule, and QC schedule	1
11/3/2003	Letter	To: L. Lee From: S. Sickafuse	Potential Review Issues (Replaces previous (Day 74 letter) )	1

**BLA 2003 Chronological Index of FDA Communications**

Date	Type	Addressee	Subject	Binder #
11/4/2003	TCR	To: Lee Pai Scherf & Mark Thornton From: L. Lee	Request for Information: Inquiry regarding ODAC	1
11/4/2003	Fax	To: L. Lee From: Mark Thornton	List of patients	1
11/7/2003	Email	To: Chana Fuchs From: N. Mehta	List of deviations associated cetuximab manufacture at	1
11/12/2003	Amendment 006	To: G. Jones From: L. Lee	Response to the first issue identified in the 10/27/03 FDA letter regarding the Dosage and Administration section of the proposed package insert.	1
11/17/2003	TCR	To: Sharon Sickafuse From: L. Lee	Discussion regarding data from BB36 materials	1
11/19/2003	TCR	To: Lee Pai Scherf From: L. Lee	Discussion regarding BB36 PK data	1
11/19/2003	Email	To: L. Lee From: Lee Pai Scherf	Tcon for PK discussion	1
11/21/2003	TCR	To: Sharon Sickafuse From: L. Lee	Updates on status of BLA amendments and reviews	1
11/24/2003	Letter	To: Lee Pai Scherf From: Debbie Lynch	2 CDs containing narratives and supporting documents for the patients with pulmonary adverse events	1
11/24/2003	Fax	To: Dr. U c/o Jose Tavaréz From: L. Lee	Update on corrective actions taken at Site 603 in response to observations noted during the FDA inspection on 10/27 - 10/31	1
11/24/2003	Fax	To: Dr. U c/o Jose Tavaréz From: L. Lee	Update on corrective actions taken at Site 600 (Van Cutsem) in response to the FDA inspection on 11/3 11/6	1
11/25/2003	Fax	To: Lee Pai Scherf From: L. Lee	Lot numbers in Section 3.2.2 of the EMR-007 Study Report	1
11/26/2003	TCR	To: Chana Fuchs From: N. Mehta	PAI, PK, Immunogenicity	1
11/26/2003	TCR	To: Debbie Trout From: N. Mehta	Cardinal PAI requests	1
11/28/2003	E-mail	To: Mark Thornton From: N. Mehta	List of Attendess from 11/25/03 Teleconference	1
11/28/2003	E-mail	To: Chana Fuchs From: N. Mehta	Immunogenicity Report for Staudy 007	1
12/2/2003	E-mail	To: David Green and Lee Pai Scherf From: Lily Lee	Password protected zip file containing the PK data requested during teleconference on November 19, 2003 (password forwarded in separate e-mail). (11:23 a.m.)	1
12/2/2003	E-mail	To: Lee Pai-Scherf and Mark Thornton From: Lily Lee	Dose Modification: Administrative Information (11:52 a.m.)	1
12/2/2003	E-mail	To: Dr. Pai-Scherf and Dr. Thornton From: L.Lee	Password protected zip file containing the dose modification for during teleconference on November 24, 2003 (password forwarded in separate e-mail)	1
12/2/2003	E-mail	To: Lee Pai-Scherf From: L.Lee	Password protected zip file containing the update of the (password forwarded in separate e-mail)	1

### BLA 2003 Chronological Index of FDA Communications

Date	Type	Addressee	Subject	Binder #
12/2/2003	TCR	To: Sharon Sickafuse From: Lily Lee	Status Updates and Additional Requests for Information re: PK Response, Dose Modification, Revised PI AE section	1
12/3/2003	Amendment 007	To: G. Jones From: L. Lee	Response to October 27, 2003 FDA "Day 74" Letter	1
12/3/2003	Letter	To: Lee Pai-Scherf From: Debbie Lynch	2 CDs containing narratives and supporting documents for the patients  Note: CDs were sent via UPS on 11/24/03 but did not make it to _____ as of 12/2/03 therefore CDs were hand delivered	1
12/4/2003	Amendment 008	To: G. Jones From: L. Lee	Responses to Requests for Information re: 1) PK Response, 2) Correction to EMR 62 202-007 PK Report, 3) Dose Modification, 4) Revision of Patient Narratives 5) Revised PI AE section, 6) Revised Clinical overview	1
12/5/2003	TCR	To: Sharon Sickafuse From: L. Lee	Discuss the BB36 PK Analysis and	1
12/9/2003	TCR	To: N.Mehta From: Debbie Trout	Request to submit information regarding the use of MDL warehouse to the BLA	1
12/8 and 12/9/03	TCR	To: Chana Fuchs From: N.Mehta, L.Lee	BLA Review	1
12/9/2003	TCR	To: Pat Keegan From: L.Lee	Request for face-to-face meeting	1
12/10/2003	Email	To: Lee Pai Scherf From: Lily Lee	Attendee List from 12/5/03 Telecon	1
12/11/2003	Email	To: Lee Pai Scherf From: Lily Lee	ERBITUX-PI Discussion Infusion Rate/Topical Seroids	1
12/11/2003	Email	To: Lee Pai Scherf From: Lily Lee	Schedule for Delivery of additional safety data for 0144	1
12/11/2003	Email	To: Lee Pai Scherf From: Lily Lee	Response to Request pertaining to recommendations in the proposed PI	1
12/11/2003	TCR	To: Pat Keegan From: L. Lee	Status of Requested Meeting	1
12/9 and 12/11/03	TCR	To: Chana Fuchs From: N. Mehta	BLA Review	1
12/11/2003	Amendment 009	To: G. Jones From: L. Lee	Process Validation Information as described in proposal given to FDA on November 14, 2003	1
12/12/2003	TCR	To: Sharon Sickafuse From: L. Lee	Confirm timing of discussion on _____ & BB36	1
12/12/2003	TCR	To: Chana Fuchs From: N. Mehta	BLA Review Update - Supplementary Process Validation submitted, Response to 483 sent out 12/12, _____ not able to attend telecon 12/16, list of facility changes to be sent, Pre-meeting package to be sent, future discussions re:	1
12/12/2003	Letter	To: Wendy Weinburg, Marlene Swider, Chana Fuchs, Debbie Trout and Edwin Martinez From: N. Mehta	Form FDA 483 Responses to observations made during the PAI of BB36 manufacturing facility	1
12/12/2003	Email	To: Chana Fuchs From: N. Mehta	List of changes at the	1

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Date	Type	Addressee	Subject	Binder #
12/12/2003	Email	To: Sharon Sickafuse, Chana Fuchs and Pat Keegan From: L. Lee	Pre-Meeting document including background information needed for 12/23/03 CMC teleconference	1
12/15/2003	TCR	To: Chana Fuchs From: N. Mehta	BLA Review - Topics to be discussed in 12/16 telecon including assay, assay, Lot Release assays	1
12/15/2003	TCR	To: Debbie Trout From: N. Mehta	BLA Review Update - Supplementary Process Validation submitted, Response to 483 sent out 12/12, Lonza and Cardinal filing 483-responses by 12/19/03, amendment for MDL to be filed by 12/19/03	1
12/15/2003	Email	To: Lee Pai Scherf From: Lily Lee	Response to Request	1
12/16/2003	Fax	To: Debbie Trout From: N. Mehta	Dye Intrusion Study Report	1
12/16/2003	TCR	To: Lily Lee From: Lee Pai Scherf	Request for additional paragraph in PI and FDA's Internal Preparation for 12/19/03 Telecon	1
12/17/2003	Email	To: L.Lee, J.Tarnowski, M.Needle, F.Fox, A.Daus, B.Hornberger, Q.Zhou, B.Saxena, Dan Lynch, M.Bloomstein, L.Yamashita, M. Birkhofer, S. Knapp, D.Smolin, C.Nicaise, O.Pfaff From: N. Mehta	Action Items from 12/16/03 telecon regarding US assay, Lot Release assays	1
12/18/2003	TCR	To: Nik Mehta From: S. Sickafuse	Comments Regarding Carton and Vial Labeling	1
12/22/2003	Amendment 010	To: G. Jones From: L. Lee	Data and recommendations section 8 (Clinical) for the proposed package insert language in response to FDA request for information	1
12/23/2003	Fax	To: Sharon Sickafuse From: L. Lee	List of attendees from 12/19/03 Teleconference	1
12/24/2003	Amendment 011	To: G. Jones From: L. Lee	CMC Information Including: 1) Protocol for testing and qualification of new Manufacturers Working Cell Banks, 2) Report on evaluation of container-closure, 3) Information on the use of MDL warehousing, 4) Updated results for on-going stability studies, 5) Confirmation that no new materials from Lonza would be released, 6) Overview of how IMClone/BMS will manage and monitor drug supply	1
12/24/2003	Email	To: Chana Fuchs From: N. Mehta	Response to question regarding the additional limit for IEF assay for stability	1
12/24/2003	Email	To: Chana Fuchs From: N. Mehta	Copy of BLA Amendment 011	1
12/29/2003	Amendment 012	To: G. Jones From: L. Lee	Revised Carton and Vial labels and Updated Lot Analysis Tables	1
12/31/2003	Email	To: C. Fuchs From: L. Lee	Responses to Questions relating to	1

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Date	Type	Addressee	Subject	Binder #
1/2/2004	TCR	To: Nik Mehta From: S. Sickafuse	Revised Carton and Vial labels found to be acceptable	2
1/5/2004	Fax/Courier	To: Sharon Sickafuse From: N. Mehta	Change in ImClone Systems' address	2
1/5/2004	Email	To: Sharon Sickafuse From: L. Lee	Comments on Proposed PI	2
1/5/2004	Email	To: Chana Fuchs From: Nik Mehta	Comments on outstanding topics	2
1/5/2004	TCR	To: Nikhil Mehta From: Wendy Weinberg for Chana Fuchs	BLA Review - HACA, IEF Assay, Endotoxin lot release assay, HCP assay	2
1/6/2004	Email	To: Lee Pai-Scherf, Sharon Sickafuse From: L. Lee	Comments on FDA's changes on Proposed PI	2
1/6/2004	Email	To: Chana Fuchs From: Nik Mehta	Meeting minutes. Follow-up discussion regarding the use of BB36 manufactured Erbitux post approval	2
1/6/2004	TCR	To: Chana Fuchs From: Nikhil Mehta & Lily Lee	BLA Review - follow-up on items submitted, format of withdrawal letter and sBLA, Agreement to use BB36 material for clinical trials, Lonza review	2
1/7/2004	Email	To: Lee Pai-Scherf From: L. Lee	Information Request - Financial Disclosure	2
1/9/2004	TCR	To: Chana Fuchs Wendy Weinberg From: Nik Mehta	BLA review	2
1/9/2004	TCR	To: Nik Mehta From: S. Sickafuse	Review topics and Revised Vial and Carton Label	2
1/12/2004	TCR	To: Chana Fuchs, Wendy Weinberg From: Nik Mehta	BLA Review	2
1/12/2004	E-mail	To: Sharon Sickafuse From: Nik Mehta	Revised Vial and Carton Label	2
1/13/2004	TCR	To: Sharon Sickafuse From: Nik Mehta	Review topics and Revised Vial and Carton Label	2
1/14/2004	TCR	To: Sharon Sickafuse From: Nik Mehta	Revised Vial and Carton Label	2
1/14/2004	TCR	To: Nik Mehta From: Debbie Trout	Cardinal 483 Response	2
1/14/2004	Email	To: Sharon Sickafuse From: Lily Lee	Revised Vial and Carton Label	2
1/15/2004	Email	To: Sharon Sickafuse From: Lily Lee	Confirmation of receipt of revised PI	2
1/15/2004	Email	To: Chana Fuchs From: Nik Mehta	(No Subject Listed in E-Mail) Reference Standard material and release specs	2
1/16/2004	Amendment 013	To: Glen Jones From: L. Lee	Revised Vial and Carton Labels, Revised Proposed Package Insert, Response to Questions on HACA Assay, Additional Financial Disclosure Information, Change of Address Notification	2
1/20/2004	Fax	To: Lily Lee From: Sharon Sickafuse	Clinical Phase 4 Commitments for Cetuximab BLA	2

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Date	Type	Addressee	Subject	Binder #
1/21/2004	E-mail	To: Lily Lee From: Lee Pai Scherf	Revised Package Insert: Version Jan. 14	2
1/21/2004	E-mail	To: Sharon Sickafuse From: Lily Lee	Response to List of Clinical Phase 4 Commitments & Milestones for Commitment 5 (Pediatric Studies)	2
1/21/2004	TCR	To: Nikhil Mehta From: Wendy Weinberg	BLA Review, Shipping conditions for drug substance from	2
1/21/2004-1/22/2004	TCR	To: Nikhil Mehta From: Marlene Swider	BLA Review, Status of Review of the Cardinal 483 Response	2
1/21/2004-1/22/2004	TCR	To: Nikhil Mehta From: Chana Fuchs	BLA Review, Withdrawal of BB36, BLA CMC Amendment,	2
1/22/2004	Email	To: Chana Fuchs From: Nikhil Mehta	Information requested to date (final amendment)	2
1/23/2004	Email	To: Chana Fuchs and Wendy Weinberg From: Nikhil Mehta	Responses to ; Questions (3:07pm)	2
1/23/2004	Email	To: Chana Fuchs From: Nikhil Mehta	5015 483 #2 update 2004- (pm)	2
1/23/2004	Email	To: Chana Fuchs From: Nikhil Mehta	Registration Numbers (6:46pm)	2
1/23/2004	TCR	To: Chana Fuchs From: Nikhil Mehta, Lily Lee, & Joe Tarnowski	BLA Review: to discuss recent question from Wendy Weinberg regarding the availability of additional process validation results for	2
1/23/2004	TCR	To: Nikhil Mehta From: Sharon Sickafuse	Review topics and Revised Vial and Carton Label	2
1/26/2004	TCR	To: Lily Lee From: Chana Fuchs	Withdrawal of BB 36	2
1/26/2004	Email	To: Sharon Sickafuse From: Chana Fuchs From: Lily Lee	Letter withdrawing BB36	2
1/27/2004	Email	To: Sharon Sickafuse From: Lily Lee	Finalization of PI - 1/27/04 changes okayed	2
1/27/2004	Amendment 014	To: Glen Jones From: L. Lee	Withdrawal of BB36, Timeline for Clinical phase 4 Commitments, Letter Requesting Accelerated Approval	2
1/28/2004	Letter	To: Sharon Sickafuse From: Nikhil Mehta	Proposed Carton & Vial Labels	2
1/28/2004	Email	To: Chana Fuchs From: Nikhil Mehta	Resin and TFF re-use	2
1/28/2004	Email	To: Sharon Sickafuse From: Nikhil Mehta	Tracking Number for Delivery, Thurs. Jan 29, 2004	2
1/28/2004	Email	To: Chana Fuchs, Wendy Weinberg From: Nikhil Mehta	Responses to questions from	2
1/28/2004	Email	To: Chana Fuchs, Wendy Weinberg From: Nikhil Mehta	Responses to questions from	2
1/29/2004	E-mail	To: Sharon Sickafuse, Pat Keegan From: Lily Lee	RE: PI? (Package Insert Correspondence)	2
1/29/2004	Email	To: Sharon Sickafuse From: Nikhil Mehta	Revised Vial and Carton Labels without latest comments	2
1/30/2004	Email	To: Sharon Sickafuse From: Nikhil Mehta	Revised Vial and Carton Labels with latest comments incorporated	2

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Date	Type	Addressee	Subject	Binder #
1/30/2004	Email	To: Sharon Sickafuse From: Nikhil Mehta	Revised Vial and Carton Labels with today's latest comments added	2
1/30/2004	Email	To: Chana Fuchs, Wendy Weinberg From: Nikhil Mehta	Updated Resin/Membrane Reuse Document	2
1/30/2004	Email	To: Sharon Sickafuse From: Nikhil Mehta	100 mg (2 mg/mL) on the carton has been bolded	2
2/2/2004	Email	To: Sharon Sickafuse From: Lily Lee	"FDA has no further comments" and plan to include latest vial and carton in 2/3/04 amendment	2
2/2/2004	Email	To: Sharon Sickafuse From: Lily Lee	Final Draft PI reflecting changes as communicated on January 30, 2004.	2
2/2/2004	Email	To: Sharon Sickafuse From: Lily Lee	Plan to send PI either in 2/3/04 amendment or final amendment	2
2/3/2004	Amendment 015	To: Glen Jones From: L. Lee	Revised Final Vial and Carton Labels, Responses to CMC review questions	2
2/3/2004	Fax	To: Lily Lee From: Sharon Sickafuse	Product PMCS - CMC Post Marketing Commitments	2
2/5/2004	Fax	To: Sharon Sickafuse From: Lily Lee	Revised Post Approval Clinical Commitments	2
2/5/2004	Email	To: Chana Fuchs; Sharon Sickafuse From: Nikhil Mehta	Post Marketing CMC Commitments	2
2/6/2004	Amendment 016	To: Glen Jones From: L. Lee	Final Draft PI, Post Marketing Commitments	2
2/12/2004	Letter	To: Lily Lee From: Sharon Sickafuse	Approval Letter - License for ImClone Systems to Manufacture Cetuximab	2
2/12/2004	Letter	To: Glen Jones From: L. Lee	Manufacturing Supplement to BLA	2
2/18/2004	Letter	To: FDA (Central Document Room, CDER) From: L. Lee	15-Day Alert Report - Mfg. Control #12502589/0	2
2/23/2004	Letter	To: Lily Lee From: Karen D. Weiss	Approval Letter - License for ImClone Systems to Manufacture Cetuximab with an Enclosure on Labeling	2
2/24/2004	Letter	To: Glen Jones From: L. Lee	Notification that regulatory reporting responsibilities for U.S. drug safety would be transferred to BMS	2
2/25/2004	TCR	To: S.Sickafuse From: Debbie Lynch	To alert CBER to the IND and BLA submissions transferring regulatory reporting responsibilities for drug safety in the U.S. to BMS	2
3/1/2004	Letter	To: FDA (Central Document Room, CDER) From: Debbie Lynch for L. Lee	15-Day Alert Report - Mfg. Control #12508859	2