

REF	PRODUC	DATE	DESCRIPTION	SERI	PROTOCOL	SUBMISSION	TYPE
52,003	Certican®	08/09/2005	TELECON confirming meeting scheduled with FDA for August 22, 2005, to discuss protocol A2310 with modeling simulations.				Memo of Record (telephone report)
52,003	Certican®	08/05/2005	[GREAT BRITAIN] Dr. Ian Judson: Gastrointestinal haemorrhage, bone marrow depression, cardiac arrest, malignant neoplasm progression, melaena, vomiting, haemoglobin decreased, platelet count decreased, dyspnoea, abdominal pain, loss of consciousness; Follow-up#3	382	2101		Safety Report
52,003	Certican®	08/05/2005	[AUSTRALIA] Dr. Dan Chambers: Vasculitis gastrointestinal, leukocytoclastic vasculitis, dermatitis allergic, neutropenia, white blood cell count decreased, diarrhoea, vomiting, intestinal ischaemia, biopsy colon abnormal, petechiae, biopsy skin abnormal; Follow-up#1	381			Safety Report
52,003	Certican®	08/03/2005	[AUSTRALIA] Dr. Dan Chambers: Vasculitis gastrointestinal, leukocytoclastic vasculitis, dermatitis allergic, neutropenia, white blood cell count decreased, diarrhoea, vomiting, intestinal ischaemia, biopsy intestine abnormal, biopsy colon abnormal, petechiae, biopsy skin abnormal.	380			Safety Report
52,003	Certican®	08/02/2005	FDA FAX containing minutes from telecon of July 21, 2005. FDA also addressed NVS request for a follow-up teleconference to discuss the heart protocol (A2310).				FDA/Novartis Meeting Minu
52,003	Certican®	07/06/2005	Dr. Judith Wolf: Hyperglycaemia; Follow-up#1.	378	C2409		Safety Report
52,003	Certican®	07/01/2005	Dr. L. Miller: Cardiac tamponade, anastomotic leak, unresponsive to verbal stimuli, fall, cardiac arrest, accelerated idioventricular rhythm; Follow-up#5	377	A2403		Safety Report
52,003	Certican®	06/30/2005	[GREAT BRITAIN] Prof. Ian Judson: Cryptogenic organizing pneumonia, lung infiltration, dyspnoea, dyspnoea exertional; Follow-up#1	376	2101		Safety Report
52,003	Certican®	06/27/2005	This submission provides a point-by-point response to the Division's comments for study CRAD001A2310 submitted February 4, 2005.	375			Clinical Information Amendr
52,003	Certican®	06/22/2005	New Protocol to Study No. CRAD001 A2309 entitled, "A 24-Month, multicenter, randomized, open-label non-inferiority study of efficacy and safety comparing concentration-controlled Certican in two doses (1.5 and 3.0 mg/day starting doses) with reduced Neoral versus 1.44 g Myfortic with standard dose of Neoral in de novo renal transplant patients.	374	A2309		New Protocol
52,003	Certican®	06/21/2005	[AUSTRALIA] Dr. Josette Eris: Drug exposure during pregnancy, premature rupture of membranes, normal delivery, hypertension; Follow-up#1.	373	A2307		Safety Report
52,003	Certican®	06/08/2005	Howard Burris, MD: Mental status changes, anaemia.	372	2101		Safety Report
52,003	Certican®	06/03/2005	TELECON with FDA in order to schedule a telecon on 21-Jul-2005 to discuss protocol A2310 (heart) statistical model and simulations for exposures. The Division will also respond to NVS proposals on A2309 (kidney) at the same time.				Memo of Record (telephone report)
52,003	Certican®	06/02/2005	Dr. L. Miller: Cardiac tamponade, anastomotic leak, unresponsive to verbal stimuli, fall, cardiac arrest, accelerated idioventricular rhythm; Follow-up#4.	371	A2403		Safety Report

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52,003	Certican®	06/02/2005	[GREAT BRITAIN] Dr. Ian Judson: Gastrointestinal haemorrhage, bone marrow depression, circulatory collapse, cardiac arrest, malignant neoplasm progression, melaena, vomiting, haemoglobin decreased, platelet count decreased, dyspnoea, abdominal pain, loss of consciousness; Follow-up#2.	370	2101	Safety Report
52,003	Certican®	06/01/2005	[AUSTRALIA] Dr. Steve Chadban: Drug exposure during pregnancy, cerebral ventricle dilatation, renal disorder, umbilical cord vascular disorder.	369	2307E1	Safety Report
52,003	Certican®	06/01/2005	[AUSTRALIA] Dr. Josette Eris: Drug exposure during pregnancy, premature rupture of membranes, normal delivery, hypertension.	368	A2307	Safety Report
52,003	Certican®	05/31/2005	[GREAT BRITAIN] Dr. Ian Judson: Gastrointestinal haemorrhage, bone marrow depression, circulatory collapse, cardiac arrest, malignant neoplasm progression, melaena, vomiting, haemoglobin decreased, platelet count decreased, dyspnoea, abdominal pain, loss of consciousness; Follow-up#1.	367	2101	Safety Report
52,003	Certican®	05/26/2005	[SWITZERLAND] Dr. D. Uehlinger: Eye haemorrhage, Retinal detachment, eye operation; Follow-up#1.	366	A2307	Safety Report
52,003	Certican®	05/20/2005	Response to request to provide questions for discussion on study CRAD001A2301.	365		Response to FDA Request
52,003	Certican®	05/19/2005	This Annual Report covers the period November 15, 2003 through November 14, 2004. Includes clinical study information, preclinical study information, Foreign marketing developments and outstanding regulatory business.	364		Annual Report
52,003	Certican®	05/16/2005	Dr. L. Miller: Cardiac tamponade, anastomotic leak, unresponsive to verbal stimuli, fall, cardiac arrest, accelerated idioventricular rhythm; Follow-up#3.	363	2403	Safety Report
52,003	Certican®	05/13/2005	Point-by-point response to the Division's comments for Study CRAD001A2309.	362		Response to FDA Request
52,003	Certican®	05/12/2005	Richard Stone. MD: Interstitial lung disease, pneumonitis, nausea, drug interaction potentiation, dyspnoea, hypoxia, pleural effusion, performance status decreased, cough, pulmonary fibrosis; Follow-up#1.	361	2207	Safety Report
52,003	Certican®	05/12/2005	Amendment No. 4 to Study No. CRAD001AUS09.	360	US09	Change In Protocol
52,003	Certican®	05/11/2005	Richard Stone. MD: Pneumonia, diarrhoea, dyspnoea, hypoxia, pleural effusion, crackles lung; Follow-up#1	359	2207	Safety Report
52,003	Certican®	05/06/2005	[SWITZERLAND] Dr. D. Uehlinger: Eye haemorrhage, retinal detachment, eye operation.	358	2307E1	Safety Report
52,003	Certican®	05/06/2005	Richard Stone: Pneumonia, hypoxia, diarrhoea, pleural effusion, dyspnoea, crackles lung.	357	2207	Safety Report
52,003	Certican®	05/05/2005	Dr. L. Miller: Cardiac tamponade, anastomotic leak, unresponsive to verbal stimuli, fall, cardiac arrest, accelerated idioventricular rhythm; Follow-up#2.	356	A2403	Safety Report
52,003	Certican®	05/05/2005	TELECON with FDA regarding Advisory Committee meeting date and the teleconference to be scheduled for the new heart study A2310 regarding modeling and simulations.			Memo of Record (telephone report)
52,003	Certican®	05/04/2005	Richard Stone, MD: Interstitial lung disease, pneumonitis, nausea, dyspnoea, hypoxia, pleural effusion, performance status decreased, cough, pulmonary fibrosis.	355	2207	Safety Report

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52,003	Certican®	05/03/2005	Dr. L. Miller: Cardiac tamponade, anastomotic leak, unresponsive to verbal stimuli, fall, cardiac arrest, accelerated idioventricular rhythm; Follow-up#1	354	2403	Safety Report
52,003	Certican®	04/28/2005	Dr. L. Miller: Cardiac tamponade, anastomotic leak, unresponsive to verbal stimuli, fall.	353	2403	Safety Report
52,003	Certican®	04/27/2005	[GREAT BRITAIN] Prof. Ian Judson: Cryptogenic organizing pneumonia, lung infiltration, dyspnoea, dyspnoea exertional.	352	2101	Safety Report
52,003	Certican®	04/24/2005	[GERMANY] Peter Reichardt: Neoplasm progression, tumour haemorrhage, haemoglobin decreased, blood lactate dehydrogenase increased, blood potassium increased, blood uric acid increased, hyperbilirubinaemia, blood creatinine increased; Follow-up#1.	350	2206	Safety Report
52,003	Certican®	04/19/2005	New Investigator to Study No. CRAD001A2401: Drs. M. Koerner, E. Hartmann, H. Shidban, J. D. Wheelchel, J. Leone, G. Basadonna. Study No. CRAD001A2403: Drs. D. Mancini, L. R. Goldberg.	349	A2401 A2403	New Investigator
52,003	Certican®	04/18/2005	[GERMANY] Peter Reichardt: Tumour lysis syndrome, tumour haemorrhage, haemoglobin decreased, blood lactate dehydrogenase increased, blood potassium increased, blood uric acid increased, hyperbilirubinaemia, blood creatinine increased.	348	2206	Safety Report
52,003	Certican®	04/08/2005	James Yao: Hypoglycaemia, feeling abnormal, confusional state.	347	BUS52	Safety Report
52,003	Certican®	04/06/2005	[GERMANY] Dr. Kaltenhaeuser: Septic shock, peripheral occlusive disease, vasculitis, drug level decreased, skin ulcer, haemoglobin decreased, C-reactive protein increased.	346		Safety Report
52,003	Certican®	04/04/2005	TELECON with FDA regarding CIOMS VI recommendations and investigator notifications from transplant and oncology indications.			Memo of Record (telephone report)
52,003	Certican®	03/28/2005	FAX from FDA containing questions on Serial Number 339, 341 and 342.			
52,003	Certican®	03/15/2005	[SWITZERLAND] Malabsorption, acne, drug interaction, drug level decreased.	345		Safety Report
52,003	Certican®	03/09/2005	New Investigator to Study No. CRAD001A2401: Drs. L. Goldberg, A. H. Wilkinson, R. Peddi, C. A. Shadur.	344	A2401	New Investigator
52,003	Certican®	03/02/2005	[CANADA] DR. Cole: Diffuse alveolar damage, cryptogenic organizing pneumonia, obliterative bronchiolitis, lung transplant rejection, cardiac arrest, pneumonia, viral infection, respiratory tract infection, pulmonary oedema, pulmonary fibrosis, respiratory disorder, haemodynamic instability, dyspnoea, hypoxia, myalgia, pyrexia, productive cough, respiratory failure, circulatory collapse.	343	A2401	Safety Report
52,003	Certican®	02/16/2005	Submission of replacement pages for the draft clinical protocol (Study CRAD001A2310) submitted February 4, 2005 (Serial No. 339).	342		Clinical Information Amendr
52,003	Certican®	02/07/2005	New Investigator to Study No. CRAD001A2405: Drs. Randall C. Starling, John M. Herre.	340	2405	New Investigator
52,003	Certican®	02/04/2005	This submission provides a point-by-point response to the Division's comments dated December 3, 2004, and contains the revised complete protocols for review and comment.			Clinical Information Amendr Response to FDA Request

REF	PRODUC	DATE	DESCRIPTION	SERI	PROTOCOL	SUBMISSION	TYPE
52,003	Certican®	01/25/2005	Letter of cross reference granting permission to the Division of Special Pathogen and Immunologic Drug Products to allow representatives from other branches of the FDA to discuss those parts of our documents relevant for Guidant's Drug Eluting Stent Investigational Device Exemptions.	338			General Correspondence
52,003	Certican®	01/14/2005	This letter authorizes the FDA to refer to this IND (and NDA 21-560 and 21-628) in support of an IND that will be filed by W. H. Tang, MD.	337			General Correspondence
52,003	Certican®	12/22/2004	New Investigator to Study No. CRAD001A2403: Dr. Leslie Miller, MD.	336	A2403		New Investigator
52,003	Certican®	12/14/2004	New Investigator to Study No. CRAD001AUS09: Dr. Oleh Pankewycz, MD. Study No. CRAD001A2401: Dr. Randall Starling.	335	US09 A2401		New Investigator
52,003	Certican®	12/09/2004	[CANADA] Dr. Cole: Diffuse alveolar damage, cryptogenic organizing pneumonia, obliterative bronchiolitis, lung transplant rejection, cardiac arrest, pneumonia, viral infection, respiratory tract infection, pulmonary oedema, pulmonary fibrosis, respiratory disorder, haemodynamic instability, dyspnoea, hypoxia, myalgia, pyrexia, productive cough; Follow-up#2.	334	2401		Safety Report
52,003	Certican®	12/03/2004	New Investigator to Study No. CRAD001A2401: Drs. P. J. Hauptman, A. Guasch, R. M. Ferguson. Study No. CRAD001A2403: Dr. G. M. Felker. Study No. CRAD001A2405: Dr. J. Kobashigawa.	333	2401 2403 2405		New Investigator
52,003	Certican®	11/05/2004	New Investigator to Study No. CRAD001US09: Drs. D. Cibrik, M. Hardy; Study No. CRAD001A2401: Drs. J. Butler, F. Wright, G. Klintmalm, K. Butt, J. A. Hill; Study No. CRAD001 A2403: Drs. B. Rayburn, F. W. Smart; Study No. CRAD001 A2405: Dr. L. Miller.	332	US09 A2401 A2403 A2405		Annual Report
52,003	Certican®	11/02/2004	Dr. Meir Wetzler, MD: Cardiac failure congestive, asthma, dyspnoea, oedema peripheral, eyelid oedema, weight increased, dilatation atrial, ventricular hypertrophy; Follow-up#1	331	2207		Safety Report
52,003	Certican®	10/29/2004	[CANADA] Dr. Cole: Lung transplant rejection, cardiac arrest, pneumonia, viral infection, respiratory tract infection, respiratory disorder, haemodynamic instability, dyspnoea, hypoxia, myalgia, productive cough; Follow-up#1	330	2401		Safety Report
52,003	Certican®	10/26/2004	New Investigator to Study No. CRAD001A2401: Drs. D. Hricik, V. G. Valentine, H. J. Eisen, T. Pruett, R. Benza, J. Curtis, P. R. Rajagopalan. Study No. CRAD001A2403: Dr. A. J. Tector.	329	A2401 A2403		New Investigator
52,003	Certican®	10/19/2004	[SPAIN] Dr. Tabernero: Malignant neoplasm progression, stomatitis, drug ineffective, enterocolitis, abdominal pain, anorexia, vomiting, constipation, skin lesion, metastases to peritoneum, performance status decreased, respiratory disorder, hypoalbuminaemia, generalised oedema; Follow-up#1.	328	C2107		Safety Report
52,003	Certican®	10/15/2004	[CANADA] Dr. Cole: Lung transplant rejection, cardiac arrest, pneumonia, respiratory tract infection, viral infection, respiratory disorder, haemodynamic instability, dyspnoea, hypoxia, myalgia, pyrexia, productive cough.	327	2401		Safety Report
52,003	Certican®	10/12/2004	Dr. Meir Wetzler, MD: Cardiac failure congestive, dyspnoea, oedema peripheral, eyelid oedema, weight increased, dilatation atrial, ventricular hypertrophy.	326	2207		Safety Report

REF	PRODUC	DATE	DESCRIPTION	SERI	PROTOCOL	SUBMISSION	TYPE
52,003	Certican®	10/01/2004	New Investigator to Study No. CRAD001A2401: Drs. B. Kahan, J. E. Loyd, A. Frost, D. J. Conti, J. M. Hare. Study No. CRAD001US09: Drs. M. T. Sellers, M. Cooper, S. Bunnapradist, V. R. Peddi, E. Hartmann, D. Norman.	325	A2401 US09	New Investigator	
52,003	Certican®	09/27/2004	Dr. Francis Giles: Leucocytoclastic vasculitis, hyperglycaemia, oedema peripheral, calcinosis; deep vein thrombosis, pain, erythema, rash, eschar.	324	2406	Safety Report	
52,003	Certican®	09/24/2004	New Investigator to Study No. US09; Drs. S. Mulgonkar, M. I. Lorber, E. Elkhammas, R. B. Love, D. G. Wombolt; Study No. 2403; Dr. H.J. Eisen; Study No. 2405; Dr. S. F. Davis.	323	US09 2403 2405	New Investigator	
52,003	Certican®	09/23/2004	[SPAIN] Dr. Tabernero: Enterocolitis, stomatitis, abdominal pain, anorexia, vomiting, constipation.	322	C2107	Safety Report	
52,003	Certican®	09/20/2004	New Investigator to Study No. CRAD001A2401: Drs. S. Mulgonkar, M. I. Lorber, E. Elkhammas, R. B. Love, D. G. Wombolt; Study No. CRAD001US09: Drs. J. Ortiz, S. Greenstein, M. I. Abecassis, G. Francos, R. Stephan.	321	A2401 US09	New Investigator	
52,003	Certican®	09/08/2004	Dr. Judith Wolf: Hyperglycaemia.	320	2409	Safety Report	
52,003	Certican®	09/03/2004	New protocol to Study No. CRAD001 A2403 entitled, "A six-Month, multicenter, randomized, Open-label Study of the Safety, Tolerability and Efficacy of two Neoral doses in addition to Certican and Steroids in de novo Heart Transplant Recipients". Investigator: Howard Eisen, MD.	319	A2403	New Protocol	
52,003	Certican®	08/27/2004	Vincent Valentine. MD: Renal failure acute, renal insufficiency, thrombocytopenia, lung transplant rejection, hyperglycaemia, blood creatinine increased, blood urea increased, fatigue, malaise, graft loss: Follow-up#1	318	B152	Safety Report	
52,003	Certican®	08/20/2004	New protocol to Study No. CRAD001 A2405 entitled, "A Six-Month, Multicenter, Open-Label, single arm, pilot study of the renal safety of Everolimus in addition to Neoral in cardiac transplant recipients with established Allograft Vasculopathy". Also, Amendment 1 to Protocol CRAD001 A2405. New Investigator: Howard Eisen, MD. And Information Amendment: New Concept design for De Novo Heart Study.	317	A2405	New Protocol	
52,003	Certican®	08/18/2004	Vincent Valentine. MD; Lung transplant rejection, renal failure acute, renal insufficiency, thrombocytopenia, hyperglycaemia, fatigue, malaise, graft loss, blood creatinine increased, blood urea increased.	316	B152E1	Safety Report	
52,003	Certican®	08/12/2004	[SWITZERLAND] Prof. W. Kiowski: Pyrexia, C-reactive protein increased, red blood cell sedimentation rate increased; Follow-up#2	315	B253	Safety Report	
52,003	Certican®	07/08/2004	Dr. George Demetri: Ascites, disease progression, drug interaction, dyspnoea; Follow-up#2	314	2206	Safety Report	
52,003	Certican®	07/02/2004	Dr. George Demetri: Ascites, disease progression, dyspnoea; Follow-up#1	313	2206	Safety Report	
52,003	Certican®	06/28/2004	Dr. George Demetri: Dyspnoea, ascites, disease progression, drug ineffective.	312	2206	Safety Report	
52,003	Certican®	06/16/2004	[BELGIUM] Dr. Van Oosterom: Gastritis haemorrhagic, right ventricular failure, pulmonary hypertension, anaemia, blood in stool, general physical health deterioration: Follow-up#2	311	2206	Safety Report	

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