Sent Date	Serial / Sequence No.	Submission Type	Correspondence Type	Submission Title
23-MAY-2006		CORRESPONDENCE	LETTER	FDA ltr. re: submission dated 24-Apr-06, SN# 132, CV181-036. FDA provides comments and requests for additional information.
24-MAY-2006	SN0137	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendment: New Investigator; Other: Change in Investigator Information re: Protocol CV181013, CV181014, CV181019, CV181038, CV181039, CV181040 and CV181020.
26-MAY-2006	SN0138	OTHER	SUBMISSION	Other: Request for FDA Review and Comment re: The Planned Core Statistical Analysis Plan (CSAP)(BMS Doc. #930014584 v1.0) for the short-term periods of the Phase # Clinical Superiority Studies. BMS request FDA input on the following protocols CV181011,CV181013, CV181014.
02-JUN-2006	SN0139	INFO AMENDMENT - CMC	SUBMISSION	Info. Amend: CMC, for additional contract packaging site to package drug products for upcoming clinical studies.
09-JUN-2006	SN0140	SAFETY REPORT: INITIAL/FOLLOW-UP	SUBMISSION	IND Safety Report - Initial written report re: Supraventricular tachycardia. Report No. 1332659
12-JUN-2006	SN0141	PROT. AMEND.: CHANGE IN PROTOCOL	SUBMISSION	Protocol Amendment - Change in Protocol for CV181-019
14-JUN-2006	SN0142	OTHER	SUBMISSION	Other - Updated Investigator Brochure version 4 dated May 18, 2006
14-JUN-2006	SN0143	INFO AMENDMENT - PHARM/TOX	SUBMISSION	Information Amendment - Pharm/Tox for Study Number DN05052
19-JUN-2006	SN0144	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendments: New Investigator re: Protocol CV181013, CV181038, CV181039, and CV181040; Other: Change in Investigator Information re: Protocol CV181011, CV181013 and CV181040.
29-JUN-2006	SN0145	INFO AMENDMENT - CMC	SUBMISSION	Information Amendment: CMC re: Information to change the dissolution method and dissolution specifications for the positive control metformin to be in line with those of the commercial Glucophage.
30-JUN-2006	SN0146	SAFETY REPORT: INITIAL/FOLLOW-UP	SUBMISSION	IND Safety Report: Initial Written Report #13387212, Anemia, 64/Male.
07-JUL-2006	SN0147	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendment: New Investigator for Protocols CV181013, CV181038, CV181039 & CV181040; Other: Change in Investigator Information for Protocols CV181013, CV181013, CV181014 & CV181040.
12-JUL-2006	SN0148	PROT. AMEND.: CHANGE IN PROTOCOL	SUBMISSION	Protocol Amendment: Change in Protocol re: Amendment #3 and Revised Protocol #02 for Protocol CV181038.
04-AUG-2006	SN0149	INFO AMENDMENT - PHARM/TOX	SUBMISSION	Information Amendment - Pharm/Tox re: study number DN05038 & DS05037.

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15-AUG-2006	SN0150	PROT. AMEND.: NEW PROTOCOL	SUBMISSION	Protocol Amendment: New Protocol, New Investigator Information Amendment: CMC re: Protocol CV181041
17-AUG-2006	SN0151	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendment: New Investigator; Other: Change in Investigator Information re: Protocol CV181013, CV181038, and CV181040.
17-AUG-2006		CORRESPONDENCE	EMAIL	FDA Email re: The agency have reviewed submission IND 63,634 SN#138 dated, 26-May-06, for saxagliptin. The submission contains protocol-specific proposed statistical analysis plan for the following three clinical studies. Protocol CV181011, CV181013, and CV181014.
06-SEP-2006	SN0152	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendment: New Investigator; Other: Change in Investigator Information re: Protocol CV181011, CV181013, CV181014, CV181038, and CV181040.
13-SEP-2006	SN0153	SAFETY REPORT: INITIAL/FOLLOW-UP	SUBMISSION	IND Safety Rpt: F/U to a written rpt. F/U#1 re: Anemia; Report No. 13387212.
14-SEP-2006	SN0154	SAFETY REPORT: INITIAL/FOLLOW-UP	SUBMISSION	IND Safety Rpt: F/U to a written rpt. F/U#2 re: Anemia; Report No. 13387212.
18-SEP-2006	SN0155	INFO AMENDMENT - PHARM/TOX	SUBMISSION	Information Amendment - Pharmocology/Toxicology re: Study Number 930016962.
18-SEP-2006	SN0156	PROT. AMEND.: CHANGE IN PROTOCOL	SUBMISSION	Protocol Amendment - Change in Protocol for CV181-040.
19-SEP-2006	SN0157	INFO AMENDMENT - CLINICAL	SUBMISSION	Information Amendment: Clinical for Study reports CV181-003, CV181-005, CV181-021 and CV181-022.
22-SEP-2006	SN0158	PROT. AMEND.: CHANGE IN PROTOCOL	SUBMISSION	Protocol Amendment: Change in Protocol for CV181-013
27-SEP-2006	SN0159	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendment: New Investigator for CV181-013, CV181-039, CV181-040 and Other: Change in Investigator Information for CV181-040.
03-OCT-2006	SN0160	PROT. AMEND.: CHANGE IN PROTOCOL	SUBMISSION	Protocol Amendment: Change in Protocol re: Amendment #04 and Revised Protocol #02 for Protocol CV181011 and Amendment #5 and Revised Protocol #02 for CV181014.
18-OCT-2006	SN0161	PROT. AMEND.: NEW PROTOCOL	SUBMISSION	Protocol Amendment: New Protocol, New Investigator Information Amendment: CMC re: Protocol CV181034
19-OCT-2006	SN0162	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendment: New Investigator; Other: Change in Investigator Information re: Protocols CV181013, and CV181040.

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20-OCT-2006		CORRESPONDENCE	LETTER	FDA ltr. re: acceptance of saxagliptin tabs into the Notice of Pilot Program.
30-OCT-2006	SN0163	SAFETY REPORT: INITIAL/FOLLOW-UP	SUBMISSION	Safety Report: Follow-up to a Written Report #13387212, Anemia, F/U #3. Protocol Study CV181014.
03-NOV-2006	SN0164	PROT. AMEND.: CHANGE IN PROTOCOL	SUBMISSION	Protocol Amendment: Change in Protocol re: Amendment #03 and Revised Protocol 02 for Protocol CV181020.
03-NOV-2006	SN0165	INFO AMENDMENT - PHARM/TOX	SUBMISSION	Information Amendment: Pharmacology/Toxicology re: Providing update to the BMS-477118 (saxagliptin, DPP4 inhibitor) 104 Week Oral Rat Carcinogenicity Study. Attached ltr is the current status and BMS's request to terminate the remaining males once the 75% mortality threshold is achieved in the combined control groups.
13-NOV-2006		CORRESPONDENCE	EMAIL	FDA Email re: Response regarding ongoing saxagliptin rat carci study.
16-NOV-2006	SN0166	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendment: New Investigator; Other: Change in Investigator Information re: Documentation (FDA form 1572 and curriculum vitae) is attached for new investigators conducting the following study protocols CV181011, CV181013, CV181014, CV181038, and CV181040.
17-NOV-2006	SN0167	INFO AMENDMENT - PHARM/TOX	SUBMISSION	Information Amendment: Pharmacology/Toxicology re: Providing the following nonclinical study reports DN03101, DS05037, and DS05194.
06-DEC-2006	SN0168	OTHER	SUBMISSION	Other: Transfer of Obligations to a Contract Research Organization re: Notification that part of the sponsor obligations have been transferred to a contract research organization for studies conducted under IND 63,634.
08-DEC-2006	SN0169	INFO AMENDMENT - CLINICAL	SUBMISSION	Information Amendment: Clinical re: Study Report CV181026 and CV181033.
08-DEC-2006	SN0170	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendment: New Investigator; Other: Change in Investigator Information re: Protocol CV181013, CV181039, and CV181040.
05-JAN-2007	SN0171	PROT. AMEND.: NEW PROTOCOL	SUBMISSION	Protocol Amendment: New Protocol, New Investigator; Information Amendment: CMC; Other: Transfer of Obligations to a Contract Research Organization re: Protocol CV181053.
05-JAN-2007	SN0172	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendment: New Investigator; Other: Change in Investigator Information re: Protocol CV181013 and CV181039.
05-JAN-2007	SN0173	SAFETY REPORT: INITIAL/FOLLOW-UP	SUBMISSION	Safety Report: Initial Written Report #13624598, Hypertensive emergency, 49/Male. Protocol Study CV181013.
12-JAN-2007	SN0175	INFO AMENDMENT - CLINICAL	SUBMISSION	Information Amendment: Clinical re: CV181004 and CV181028.

Sent Date	Serial / Sequence No.	Submission Type	Correspondence Type	Submission Title
12-JAN-2007	SN0174	PROT. AMEND.: CHANGE IN PROTOCOL	SUBMISSION	Protocol Amendment: Change in protocol re: CV181-041
19-JAN-2007	SN0176	PROT. AMEND.: CHANGE IN PROTOCOL	SUBMISSION	Protocol Amendment: Change in Protocol re: CV181-019
23-JAN-2007	SN0177	SAFETY REPORT: INITIAL/FOLLOW-UP	SUBMISSION	Safety Report: Follow-up to a Written Report #13624598, Hypertensive emergency, F/U #1, for Protocol CV181013.
24-JAN-2007		CORRESPONDENCE	TELEPHONE	FDA Telephone Contact Report; re: AB called 19-Jan-07 & left a voicemail to call her which was returned 24-Jan-07. She requested a revisit target submission date with an explanation for the Saxagliptin NDA. AB requested that BMS submit to the Docket our revised target date for NDA submission with an explanation for submission timing and cc. her of the coores.; next step is for SL to provide requested info. to Docket with cc. to AB
05-FEB-2007	SN0178	ANNUAL REPORT	SUBMISSION	Annual Report covers the period 01-Dec-05 to 30-Nov-06.
07-FEB-2007	SN0179	SAFETY REPORT: INITIAL/FOLLOW-UP	SUBMISSION	IND Safety Report: Follow-Up to a Written Report; re: IND app. for BMS-477118; study CV181014, report # 13387212 (Anemia) Follow up #4
21-FEB-2007	SN0180	SAFETY REPORT: INITIAL/FOLLOW-UP	SUBMISSION	IND safety report: Initial written report re: Myocardial ischaemia, for 57 year old male; Report No. 13674361.
01-MAR-2007	SN0181	OTHER	SUBMISSION	Other: CMC Information Type C Meeting Request re: Requests a 90-minute Type C mtg to discuss our on-going Quality-by-Design development efforts for saxagliptin tablets.
01-MAR-2007	SN0182	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendment: New Investigator; Other: Change in Investigator Information re: Protocol CV181013, CV181014, CV181020, CV181038, CV181040, and CV181041.
05-MAR-2007	SN0183	INFO AMENDMENT - PHARM/TOX	SUBMISSION	Information Amendment: Pharmacology/Toxicology re: Nonclinical study reports, Study #DS06118, DN05018, DN05020, DN05033, 930016963, DN05063, and DS04187.
05-MAR-2007		CORRESPONDENCE	EMAIL	BMS Internal: BMS Email re: Attached ltr from FDA regarding the Agency's request to update language in the IB and IC to include additional information on nonclinical findings in dogs, rats, monkeys and clinical findings reported for one or more other DPP4 inhibitor compounds in development.
07-MAR-2007		CORRESPONDENCE	LETTER	FDA Ltr. re: The agency has received data indicating that the administration of dipeptidyl peptidase-4 (DPP-4) inhibitors to monkeys results in dose and duration-dependent increases n necrotizing cutaneous lesions of the periphery, including the tail, digits, hands/feet, ears, nose, and scrotum.

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12-MAR-2007	SN0184	SAFETY REPORT: INITIAL/FOLLOW-UP	SUBMISSION	Safety Report: Initial Written Report: Safety Report: Follow-up to a Written Report #13694740, Cellulitis, 57/Male. Protocul Study CV181038.
13-MAR-2007	SN0185	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendment: New Investigator; Other: Change in Investigator Information re: Protocol CV181013, CV181038, CV181039, and CV181040.
15-MAR-2007		CORRESPONDENCE	LETTER	FDA letter re: FDA approval for a Type C meeting with BMS, to discuss the quality portion of the upcoming NDA , as part of the CMC pilot program
05-APR-2007	SN0186	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amendment: New Investigator; Other: Change in Investigator Information re: Protocol CV181013, CV181039, CV181011, and CV181014.
05-APR-2007	SN0187	PROT. AMEND.: CHANGE IN PROTOCOL	SUBMISSION	Protocol Amendment: Change in Protocol re: Amendment #05 for the following clinical study: Protocol CV181039.
11-APR-2007	SN0188	OTHER	SUBMISSION	Other: Briefing Document for CMC-Type C Meeting for 26-Apr-07 is provided.
11-APR-2007		CORRESPONDENCE	TELEPHONE	FDA Telephone Contact re: Status of BMS proposal for conducting a definitive QT Study.
12-APR-2007	SN0189	OTHER	SUBMISSION	Other: Request for Review and Comment - CMC provides additional bkg information in support of BMS proposed starting materials for the drug substance synthesis.
19-APR-2007	SN0190	SAFETY REPORT: INITIAL/FOLLOW-UP	SUBMISSION	Safety Report: Initial Written Report #13739800, Pancreatitis acute, 63/Female for Protocol CV181039.
19-APR-2007		CORRESPONDENCE	LETTER	FDA Ltr. re: Amendment dated 22-Jan-07 (serial #0011), containing proposed QTc evaluation plan. QTc Team has completed their review of submission and has the following comments and recommendations.
03-MAY-2007	SN0191	SAFETY REPORT: INITIAL/FOLLOW-UP	SUBMISSION	Safety Report: Followup to a Written Report #13739800, Pancreatitis acute Gastritis erosive, F/U #1. Protocol CV181039.
03-MAY-2007	SN0192	PROT. AMEND.: NEW INVESTIGATOR	SUBMISSION	Protocol Amend.: New Investigator/Other: Change of Investigator Info.; re: protocol CV181011 & CV181013
03-MAY-2007		CORRESPONDENCE	EMAIL	FDA Email re: Saxagliptin, IND 63,634 Amendment dated 12-Apr-07.
03-MAY-2007		CORRESPONDENCE	EMAIL	BMS Internal: BMS Email re: FDA/BMS Saxagliptin QbD Meeting Contact Report.
08-MAY-2007	SN0193	PROT. AMEND.: CHANGE IN PROTOCOL	SUBMISSION	Protocol Amend.: Change in Protocol; re: IND app. for BMS-477118, protocol CV181018, CV181020, & CV181035

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