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Date	Brief Description of Significant Activities
98-0521	Submitted first protocol
98-0618	Amgen pre-IND meeting notes submitted. Concurrence from the Division and any comments on the Contents are requested.
98-0722	Protocol Amendment: Change in Protocol and added New Investigators
98-0810	Protocol Amendment: New Protocol
98-0814	Information Amendment: Pharm/Tox: Carcinogenicity Studies Plan for CAC review submitted as discussed in pre-IND meeting
98-0820	Protocol Amendment: Added New Investigators Information Amendment: Pharm/Tox
98-0826	Request for information on Carcinogenicity Studies Plan
98-0827	Information Amendment: Pharm/Tox: Response to Questions followed up by teleconference
98-0828	Telephone review of pending protocols of ADME radiolabeled study parenteral formulation
98-0901	Request for interim data from rat study.
98-0902	Information Amendment: Pharm/Tox: Response to Questions; Requested data faxed and mailed following verbal preview.
98-0918 98-0921	Telephone exchange re status of carcinogenicity study proposal.
98-0921	Telephone exchanges to request discussion of radiolabeled ADME study with senior chemist.
98-0922	Review Amgen carcinogenicity studies proposal
98-0924	Protocol Amendment: added new investigators
98-1014 98-1015 98-1016 98-1019	Carcinogenicity studies proposal and findings of CDER Exec CAC re. dosing
98-1020	Phone confirmation of letter being prepared re. carcinogenicity studies agreement reached on 98-1016
98-1022	Monthly Package with a New Protocol and New Investigators for Protocols. New Protocol: drug interaction study
98-1106	2 Protocol Amendments (updated informed consents) and 1 New Protocol (ADME radiolabeled study)
98-1201	Protocol Amendment: Change in a protocol.

98-1223	Protocol Amendment
99-0105	Submitted additional CMC information relative to ADME radiolabeled study
99-0112	Telephone discussion re request for teleconference on protocol synopsis.
990122	Protocol Amendment: New investigators
99-0203	Telephone discussion re request for teleconference on protocol synopsis.
990217	Teleconference to discuss proposed Phase 2 protocol synopsis
99-0222	Telephone discussion re teleconference on protocol synopsis.
99-0225	Protocol Amendment
99-0301	Information Amendment: Draft statistical section submitted per agreement in Feb. 17, 1999 teleconference
99-0301	Fax transmission of data tables per discussion with FDA held on Feb. 26, 1999
99-0302	Information Amendment: Pharmacology-Toxicology; Submission of summary tables
99-0308	Telephone conversation re summary tables of kidney and liver toxicology data
99-0401	Protocol Amendment: New Protocol
99-0407	Information Amendment: CMC tablet formulations
99-0409	FDA's meeting minutes of the teleconference held on February 17, 1999 to discuss the protocol synopsis
99-0414	Protocol Amendment: New Protocol
99-0421	Protocol Amendment: New Investigators
99-0522	Protocol Amendment: Change in Protocol and Amended Site information
99-0615	Information Amendment: CMC capsule formulation
99-0618	Protocol Amendment: Change in Protocol, New Investigators and Amended Site information
99-0716	Protocol Amendment: New Investigators and Amended Site information
99-0813	Protocol Amendment: New Protocols
99-0818	Protocol Amendment: New Investigators and Amended Site information
99-0920	Protocol Amendment: New Investigators and Amended Site information
99-1006	Information Amendment: Chemistry Manufacturing and Control
99-1019	Protocol Amendment: New Investigators and Amended Site information

99-1025	Protocol Amendment: New Protocol
99-1116	FDA request for Information re. Protocol Amendment
99-1116	Response to FDA request for Information
99-1117	FDA request for information re. Information Amendment of March 1
99-1119	Protocol Amendment: New Protocol
99-1119	Protocol Amendment: New Investigator
99-1124	Information Amendment: Submission of FINAL toxicology study reports
99-1213	FDA request for information re. dose selection. Responded in voice mail message.
99-1215	Information Amendment: Pharm/Tox
99-1220	Protocol Amendment: Change in Protocol & New Investigators
00-0104	Response to FDA request for Information of Nov. 17, 1999
00-0105	FDA request for information
00-0105	FAX: response to request for information
00-0106	FAX: additional response to request for information
00-0106	Response to FDA request for Information; Submission of additional pharm/tox data
00-0120	Protocol Amendment: New Investigators
00-0201	Protocol Amendment: New Protocol
00-0207	FDA request for information
00-0216	Information Amendment: Revised SAP for Protocol per agreement
00-0217	Protocol Amendment: New Investigators
00-0225	FDA request for information
00-0225	Information Amendment: report on the on-going carcinogenicity studies
00-0229	Protocol Amendment: New Protocol
00-0307	Protocol Amendment: Change in Protocol
00-0317	Response to FDA Comments dated Feb 7 2000
00-0321	Protocol Amendment: New Investigators
00-0405	Response to FDA Comments dated Feb 25 2000
00-0405	Protocol Amendment: New Protocol
00-0414	Protocol Amendment: New Investigators
00-0508	Protocol Amendment: New Protocol
00-0523	Protocol Amendment: Change in Protocol
00-0526	Protocol Amendment: New Investigators
00-0601	Protocol Amendment: Change in Protocol
00-0607	Protocol Amendment: New Protocol and Information Amendment

	CMC manufacturing process
00-0620	Protocol Amendment: New Protocol and Information Amendment CMC tablet formulation
00-0621	Protocol Amendment: New Investigators
00-0727	Protocol Amendment: Change in Protocol and New Investigators
00-0803	IND Safety Report
00-0809	IND Safety Report
00-0818	Protocol Amendment: New Protocol; Open label extension for primary HPT
00-0823	Protocol Amendment: New Investigators
00-0914	FDA request for information re. CMC information
00-0919	Protocol Amendment: New Investigators
00-1004	Protocol Amendment: New Protocol
00-1013	Protocol Amendment: Change Protocol
00-1017	Protocol Amendment: New Investigators
00-1018	Information Amendment: Chemistry Manufacturing Control
00-1019	Protocol Amendment: New Protocol
00-1122	Protocol Amendment: New Investigators
00-1221	Protocol Amendment: New Investigators
00-1222	Protocol Amendment: New Protocol
00-1222	Protocol Amendment: Change Protocol
00-1229	Protocol Amendment: New Protocol
01-0102	Protocol Amendment: Change Protocol
01-0108	Protocol Amendment: New Protocol
01-0110	Protocol Amendment: Change Protocol
01-0122	Protocol Amendment: New Investigators
01-0222	Protocol Amendment: Change Protocol
01-0222	Protocol Amendment: Change Protocol
01-0227	Protocol Amendment: New Investigators
01-0302	Protocol Amendment: New Protocol
01-0306	Protocol Amendment: Change in Protocol
01-0312	Protocol Amendment: Change in Protocol and Information Amendment CMC
01-0314	Protocol Amendment: New Protocol and Information Amendment CMC

01-0316	Protocol Amendment: New Protocol
01-0320	Response to FDA Request for Information dated March 5, 2001
01-0321	Protocol Amendment: New Investigators
01-0327	Protocol Amendment: Change in Protocol
01-0328	Protocol Amendment: Change in Protocol
01-0420	Protocol Amendment: New Investigators
01-0510	Protocol Amendment: New Protocol
01-0521	Protocol Amendment: New Investigators
01-0614	Protocol Amendment: New Protocol
01-0619	Protocol Amendment: New Investigators
01-0626	Protocol Amendment: Change in Protocol
01-0719	Protocol Amendment: New Protocol
01-0723	Protocol Amendment: New Investigators
01-0730	Protocol Amendment: Change in Protocol
01-0806	Phone call re. Protocol Amendment of July 30
01-0815	Response to query; Follow-up to action items noted in the Agency's minutes of the June 6 2001 CMC meeting
01-0817	Protocol Amendment: New Investigators
01-0913	Response to Query of August 6
01-0921	Protocol Amendment: New Investigators
01-0927	Protocol Amendment: New Protocol
01-1023	Protocol Amendment: New Protocol
01-1024	Protocol Amendment: New Investigators
01-1025	Protocol Amendment: New Protocol
01-1025	Protocol Amendment: New Protocol
01-1029	Response to Query of Sept. 14, 2000 & Information Amendment: Chemistry Manufacturing Control
01-1030	Protocol Amendment: Change in Protocol
01-1116	Protocol Amendment: New Investigators
01-1129	Protocol Amendment: Change in Protocol
01-1221	Protocol Amendment: New Investigators
01-1226	Protocol Amendment: New Protocol
02-0122	Protocol Amendment: New Investigators
02-0129	Protocol Amendment: Change in Protocol
02-0206	FDA requested information package to allow assessment of the statistical analysis plan for the Patient Reported Outcomes (PRO) data collected in the phase 3 program
02-0206	FDA request for information pertaining to the Patient Reported

	Outcomes (PRO) program
02-0206	FDA question pertaining to changes in hormone levels observed in the one-year monkey study
02-0209	Response to Question Submitted information pertaining to the Patient Reported Outcomes (PRO) program
02-0220	Protocol Amendment: Change in Protocol
02-0221	Protocol Amendment: New Investigators
02-0304	Submission of package per Agency request of February 6
02-0320	FDA posed questions based documents dated March 4 2002, providing information on Patient Reported Outcomes (PRO) program
02-0321	General Correspondence: High-level summary of outcome of March 21, 2002 teleconference. Detailed meeting minutes to follow.
02-0321	Protocol Amendment: New Protocol
02-0325	Protocol Amendment: New Investigators
02-0326	General Correspondence: Meeting minutes of March 21, 2002 teleconference
02-0404 02-0405	FDA contacted Amgen to ask when the Agency could expect to receive a study protocol to review the proposed analysis plan for that study. Amgen provided via fax the stat. Section of a similar protocol.
02-0418	Protocol Amendment: New Investigators
02-0419	Protocol Amendment: New Protocol
02-0419	Response to FDA Request for Information of April 4, 2002
02-0503	Protocol Amendment: Change in Protocol
02-0513	Protocol Amendment: Change in Protocol
02-0521	Protocol Amendment: New Investigators
02-0604	Information Amendment: Statistical Analysis Plan for Phase 3 study
02-0624	Protocol Amendment: New Investigators
02-0718	Protocol Amendment: New Investigators
02-0802	Protocol Amendment: Change in Protocol
02-0906	Protocol Amendment: New Investigators
02-0909	Protocol Amendment: New Protocol
02-0930	Protocol Amendment: New Investigators
02-1024	Protocol Amendment: New Investigators
02-1122	Protocol Amendment: New Investigators
02-1220	Protocol Amendment: New Investigators
03-1229	Teleconference to discuss study data
03-0124	Protocol Amendment: New Investigators
03-0224	Protocol Amendment: New Investigators

03-0327	Protocol Amendment: New & Revised Investigator Information
03-0401	Response to FDA Request for Information: Submitted Information Package for FDA review and comment as requested by FDA on Mar 28 2003
03-0415	Information Amendment: Revised Phase 3 Statistical Analysis Plan
03-0415	Amgen follow up communication regarding FDA review of Information Package dated April 1, 2003.
03-0418	Protocol Amendment: New & Revised Investigator Data
03-0422	FDA response to Information Package dated April 1, 2003.
03-0422	Information Amendment: Revised statistical analysis plan
03-0424	Information Amendment: Revised Phase 3 Statistical Analysis Plan
03-0508	Protocol Amendment: New Protocol
03-0523	Protocol Amendment: New and Revised Investigator Information
03-0620	Protocol Amendment: New and Revised Investigator Information
03-0624	Information Amendment: Chemistry, Manufacturing, and Controls update
03-0702	Information Amendment: Revised Statistical Analysis Plans
03-0702	Protocol Amendment: Change in Protocol
03-0714	Protocol Amendment: New Protocol
03-0717	Protocol Amendment: New and Revised Investigator Information
03-0821	Protocol Amendment: New and Revised Investigator Data
03-0821	Response to FDA Request for Information: Rationale for Priority Review for the NDA
03-0905	NDA Filed
03-0918	Protocol Amendment: New and Revised Investigator Data
03-0922	Protocol Amendment: Change in Protocol
04-0308	NDA Approved following 6 month FDA review