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| Date | Brief Description of Significant Activities |
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| 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. |

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| 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 |

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| 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 |

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| | 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 |

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| 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 |

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| | 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 |

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| 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 |
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