REF	PRODUC	DATE	DESCRIPTION	SERI	PROTOCOL	SUBMISSION TYPE
66,279	RAD 001C	02/26/2007	Novartis Pharmaceuticals Corporation authorizes the FDA to refer to IND 66,279 RAD001 (everolimus) Tablets in support of an Investigational New Drug Application (IND) that will be filed by Bert O'Neil , M.D. (PS)	299		Other
66,279	RAD 001C	02/26/2007	Novartis Pharmaceuticals Corporation authorizes the FDA to refer to IND 66,279 RAD001 (everolimus) Tablets in support of an Investigational New Drug Application (IND) that will be filed by Srdan Verstovsek, M,D., Ph.D. (PS)	300		Other
66,279	RAD 001C	02/26/2007	Novartis Pharmaceuticals Corporation authorizes the FDA to refer to IND 66,279 RAD001 (everolimus) Tablets in support of an Investigational New Drug Application (IND) that will be filed by Johanna Bendell, M.D. (PS)	301		Other
66,279	RAD 001C	02/22/2007	FDA LETTER Responses to the November 6, 2006, serial number 252, request for SPA.			Other
66,279	RAD 001C	02/22/2007	PHHO2007CA02219; follow-up (PS)	296		Safety Report
66,279	RAD 001C	02/22/2007	This Annual report covers the period December 25, 2005 through December 24, 2006 (PS)	297		Annual Report
66,279	RAD 001C	02/20/2007	Email from FDA responding to Novartis' question regarding the PPSR being submitted.			Other
66,279	RAD 001C	02/19/2007	Proposed Pediatric Study Request submiited for the treatment of refractory cancers in a pediatric population (ages 3-16) (Protocol No. CRAD001C2244) (PS)	294		Other
66,279	RAD 001C	02/19/2007	New investigators to Study CRAD001C2114, CRAD001C2240 and CRAD001C2241 (PS)	295		New Investigator
66,279	RAD 001C	02/19/2007	This annual report covers the period November 27, 2006 through November 26, 2007. (PS)	547		Annual Report
66,279	RAD 001C	02/15/2007	PHBS2006AT07989; follow-up (PS)	293		Safety Report
66,279	RAD 001C	02/13/2007	At this time, Novartis is submitting an IND amendment to provide updated information on the manufacturing sites, stability programs, and other CMC changes. The summary of changes and the updated IND sections are included in this submission (PS)	292		CMC Amendment
66,279	RAD 001C	02/09/2007	PHHO2007CA02219; follow-up (PS)	290		Safety Report
66,279	RAD 001C	02/09/2007	New Protocol RAD001C2242 entitled: "An open-label, multicenter Phase 1 study investigating the combination of RAD001, cetuximab and irinotecan as second-line therapy after FOLFOX (or XELOX) plus bevacinunab (if given as part of local standard practice) in patients with metastatic colorectal adenocarcinoma" (PS)	291		New Protocol
66,279	RAD 001C	02/08/2007	Novartis Pharmaceuticals Corporation authorizes FDA to refer to IND 66279 for RAD001 (everolimus) in support of an Investigational New Drug Application (IND) that will be filed by Dr. Mark Stein (PS)	289		Other
66,279	RAD 001C	02/08/2007	PHHO2007CA02219; follow-up (PS)	288		Safety Report
66,279	RAD 001C	02/07/2007	PHHO2007CA02219 (PS)	287		Safety Report
66,279	RAD 001C	02/06/2007	Novartis Pharmaceuticals Corporation authorizes the FDA to refer to IND 66,279 RAD001 (everolimus) Tablets in support of an Investigational New Drug Application (IND) that will be filed by Daniel George, MD (PS)	285		Other

REF	PRODUC	DATE	DESCRIPTION	SERI	PROTOCOL	SUBMISSION TYPE
66,279	RAD 001C	02/06/2007	Novartis Pharmaceuticals Corporation authorizes the FDA to refer to IND 66,279 RAD001 (everolimus) Tablets in support of an Investigational New Drug Application (IND) that will be filed by Jorae A. Ciarcia. MD (PS)	286		Other
66,279	RAD 001C	02/05/2007	New investigators to Study CRAD001C2239 and CRAD001C2240 (PS)	284		New Investigator
66,279	RAD 001C	02/01/2007	PHHO2004BE07879; follow-up (PS)	283		Safety Report
66,279	RAD 001C	01/29/2007	This submissions contains copies of the materials sent on January 25, 2007, serial number 280 (PS)	282		General Correspondence
66,279	RAD 001C	01/26/2007	Email to FDA informing them that the materials sent via email have been sent directly to them instead of the central document room.			Response to FDA Request
66,279	RAD 001C	01/26/2007	PHHO2006US22076; follow-up (PS)	281		Safety Report
66,279	RAD 001C	01/25/2007	PHHO2007US00556; follow-up (PS)	279		Safety Report
66,279	RAD 001C	01/19/2007	PHHO2006US22076 (PS)	278		Safety Report
66,279	RAD 001C	01/18/2007	New investigator/Sub investigator to Study CRAD001C2111 (PS)	276		New Investigator
66,279	RAD 001C	01/18/2007	PHHO2007US00556 (PS)	277		Safety Report
66,279	RAD 001C	01/17/2007	Email to FDA informing them of the upcoming Novartis FDA CRADA meeting.			Other
66,279	RAD 001C	01/16/2007	Email from FDA replying to the meeting cancellation of the January 18, 2007 Type A meeting.			Other
66,279	RAD 001C	01/16/2007	New investigator to Study CRAD001C2239 and CRAD001C2325. New investigators to Study CRAD001C2240 (PS)	275		New Investigator
66,279	RAD 001C	01/09/2007	This correspondence is to provide the FDA with Novartis' questions for the Type A meeting which is scheduled for January 18, 2007 (ES)			General Correspondence
66,279	RAD 001C	01/03/2007	Email to FDA containing serial number 274, an addendum to the briefing book (ES)			General Correspondence
66,279	RAD 001C	01/03/2007	The addendum the the briefing book contains simulation data which is highly relevant to the planned discussions and the conclusions are supportive of the Novartis position as stated in the protocol. Please note that this submission in REDI only contains the cover letter and 1571, as this is all we received for archiving). (PS)	274		Other
66,279	RAD 001C	01/01/2007	Email from FDA responding to Novartis' questions regarding the FDA information request for the simulation methods.			Other
66,279	RAD 001C	12/28/2006	PHHO2006FR20729; Follow-up	273		Safety Report
66,279	RAD 001C	12/22/2006	Email from FDA with responses to Novartis' questions regarding protocol CRAD001C2325			Other
66,279	RAD 001C	12/22/2006	PHHO2005DE16006; Follow-Up	272		Safety Report
66,279	RAD 001C	12/21/2006	New investigator to Study CRAD001C2239 and CRAD001C2241, new investigators to Study CRAD001C2240 (PS)	271		New Investigator
66,279	RAD 001C	12/21/2006	PHHO2006FR20729; Follow-up	270		Safety Report

REF	PRODUC	DATE	DESCRIPTION	SERI	PROTOCOL	SUBMISSION TYPE
66,279	RAD 001C	12/21/2006	PHBS2006ES19190; Follow-Up	269		Safety Report
66,279	RAD 001C	12/21/2006	PHBS2006ES19166; Follow-Up	268		Safety Report
66,279	RAD 001C	12/20/2006	Amendment No. 2 to Protocol CRAD001C2239 (PS)	267		Change In Protocol
66,279	RAD 001C	12/18/2006	PHHO2006FR20566; Follow-Up	266		Safety Report
66,279	RAD 001C	12/18/2006	PHHO2006IT15311; Follow-Up	265		Safety Report
66,279	RAD 001C	12/13/2006	Novartis Pharmaceuticals Corporation authorizes the FDA to refer to IND 66,279 RAD001 (everolimus) Tablets in support of an Investigational New Drug Application (IND) that will be filed by Gabriela Chiorean, MD (PS)	264		Other
66,279	RAD 001C	12/12/2006	In response to FDA request the email contains the questions q posed in BB submitted with SPA for CRAD001C2325 (RAD001 in Carcinoid IND66,279) on Nov 6, 2006 (Serial 252) (ES)			Response to FDA Request
66,279	RAD 001C	12/12/2006	PHHO2006US17466; follow-up (PS)	263		Safety Report
66,279	RAD 001C	12/12/2006	New investigator to Study CRAD001C2111, CRAD001C2239, and new investigators to CRAD001C2241 (PS)	262		New Investigator
66,279	RAD 001C	12/08/2006	PHHO2006IT15311; follow-up (PS)	260		Safety Report
66,279	RAD 001C	12/08/2006	This correspondence is to inform the FDA of the transfer of specific obligations to a contract research organization for clinical drug supply management of selected sites in protocol CRAD001C2240 (PS)	261		General Correspondence
66,279	RAD 001C	12/07/2006	New investigators to Study CRAD001C2239 (PS)	259		New Investigator
66,279	RAD 001C	12/07/2006	Fax from FDA containing the Medical imaging responses to serial number 249.			Other
66,279	RAD 001C	12/06/2006	PHHO2006US11747; follow-up (PS)	258		Safety Report
66,279	RAD 001C	11/21/2006	Email from FDA confirming the postponement of the November 27, 2006teleconference to January 18, 2007.			Other
66,279	RAD 001C	11/16/2006	Email response to the FDA request for a copy of the draft IRC charter for CRAD001C2239 protocol.			Response to FDA Request
66,279	RAD 001C	11/15/2006	Amendment No. 1 to Protocol RAD001C2235 (PS)	257		Change In Protocol
66,279	RAD 001C	11/09/2006	PHHO2004US12965; follow-up (PS)	256		Safety Report
66,279	RAD 001C	11/07/2006	This submission contains RAD001C Investigator's Brochure Edition 5 (PS)	253		Clinical Information Amendr
66,279	RAD 001C	11/07/2006	New investigator to Study CRAD001C2206 (PS)	254		New Investigator
66,279	RAD 001C	11/07/2006	PHHO2006US17466; Follow-Up (PS)	255		Safety Report
66,279	RAD 001C	11/06/2006	Request for special protocol assessment for Study CRAD001C2325 (PS)	252		Other
66,279	RAD 001C	10/31/2006	PHHO2006US17466 (PS)	251		Safety Report
66,279	RAD 001C	10/24/2006	Briefing Book is being submitted in preparation for the Type A meeting to gain clarification on FDA's responses , provide clarification on Novartis position and ensure agreement on any additional modifications which may be required to allow for a positive agency determination regarding protocol CRAD001C2240 and allow the study to proceed (PS)	249		Briefing Book

REF	PRODUC	DATE	DESCRIPTION	SERI	PROTOCOL	SUBMISSION TYPE
66,279	RAD 001C	10/24/2006	PHBS2006ES15520; follow-up (PS)	250		Safety Report
66,279	RAD 001C	10/23/2006	Email responding to FDA that Novartis acknowledges receipt of the e-mail and the proposed date of the meeting for November 27th 2PM.			Other
66,279	RAD 001C	10/23/2006	Email to FDA regarding the number of copies needed of the briefing book and the meeting date of November 10, 2006 for the Type A meeting.			Other
66,279	RAD 001C	10/23/2006	PHHO2006US11747; follow-up (PS)	248		Safety Report
66,279	RAD 001C	10/23/2006	Novartis Pharmaceuticals Corporation authorizes the FDA to refer to IND 66,279 RAD001 (everolimus) Tablets in support of an Investigational New Drug Application (IND) that will be filed by Andrew X. Zhu, MD, PhD (PS)	247		Other
66,279	RAD 001C	10/20/2006	Email response to the FDA request for an electronic copy of the Type A meeting request.			Request for FDA Meeting
66,279	RAD 001C	10/17/2006	PHBS2006S15520; Follow-up (PS)	246		Safety Report
66,279	RAD 001C	10/13/2006	Novartis Pharmaceuticals Corporation authorizes the FDA to refer to IND 66,279 RAD001 (everolimus) Tablets in support of an Investigational New Drug Application (IND) that will be filed by Barbara Burtness, MD (PS)	245		Other
66,279	RAD 001C	10/09/2006	Type A meeting request to gain further clarification on the responses received by the FDA, particularly for questions 3, 7 and 11. More specifically Novartis wishes to identify any additional modifications to the proposed pivotal study, analysis plan and independent radiological review charter necessary to adequately meet the requirements for a regulatory submission of phase III protocol CRAD001C2240 data in support of approval of RAD001 for the treatment of patients with metastatic renal cell carcinomas who have	244		Request for FDA Meeting
66,279	RAD 001C	10/06/2006	PHHO2006IT15311 (PS)	243		Safety Report
66,279	RAD 001C	10/03/2006	New investigator to Study No. RAD001C2239 (PS)	241		New Investigator
66,279	RAD 001C	10/03/2006	PHHO2006IT15311 (PS)	242		Safety Report
66,279	RAD 001C	09/29/2006	PHHO2006IT09039; Follow Up (PS)	240		Safety Report
66,279	RAD 001C	09/27/2006	Addressing issues raised per September 26, 2006 phone call noting discrepancies between information Novartis submitted and the FDA website so that Entry 506-0814195-3 can be released. (PS)			Other
66,279	RAD 001C	09/25/2006	New investigator to Study No. RAD001C2206 and new investigators to Study No. RAD001C2239 (PS)	239		New Investigator
66,279	RAD 001C	09/19/2006	New Protocol RAD001J2101 entitled: "A phase Ib study investigating the combination of AD001 with trastuzumab and paclitaxel in patients with HER2-overexpressing metastatic breast cancer" (PS)	238		New Protocol
66,279	RAD 001C	09/15/2006	FDA LETTER response to SPA for CRAD001C2240 (PS)			Other
66,279	RAD 001C	09/13/2006	New Protocol RAD001C2114 entitled, "A two-step phase 1 study investigating the combination of RAD001 with carboplatin, paclitaxel and bevacizumab in non-small-cell lung cancer (NSCLC) patients not treated previously with systemic therapy (PS)	236		New Protocol

REF	PRODUC	DATE	DESCRIPTION	SERI	PROTOCOL	SUBMISSION TYPE
66,279	RAD 001C	09/13/2006	New Protocol RAD001C2116 entitled: " A phase Ib study investigating the combination of RAD001 with cisplatin and etoposide in patients with extensive-stage small-cell lung cancer not previously treated with chemotherapy" (PS)	237		New Protocol
66,279	RAD 001C	09/07/2006	TELECON with FDA on September 7, 2006 to discuss the request for ane e-copy of the CRAD001C2240 SPA and the timelines for FDA review/response of Oncology PPSR (PS)			Memo of Record (telephone report)
66,279	RAD 001C	09/07/2006	Email regarding the request from FDA for an electronic copy fo the SPA for protocol CRAD001C2240 (PS)			Response to FDA Request
66,279	RAD 001C	08/31/2006	PHHO2006US02640; follow-up (PS)	234		Safety Report
66,279	RAD 001C	08/31/2006	Novartis Pharmaceuticals Corporation hereby authorizes the FDA to refer to IND 66,279 RAD001 (everolimus) Tablets in support of an Investigational New Drug Application (IND) that will be filed by John D. Hainsworth, M.D. (PS)	235		Other
66,279	RAD 001C	08/29/2006	New investigator to Study No. CRAD001C2206 (PS)	233		New Investigator
66,279	RAD 001C	08/23/2006	Email response to FDA request for TOC and and electronic copy of the 11 protocol specific questions listed in section 5 of the briefing book submitted on July 28, 2006 (PS)			Response to FDA Request
66,279	RAD 001C	08/22/2006	New Protocol, RAD001C2241 entitled, "A single erm, multicenter phase II study of RAD001 in patients with metastatic colorectal adenocarcinoma whose cancer has progressed despite prior therapy with an anti- EGFR antibody (if appropriate), bevacizumab, fluoropyrimidine, oxaliplatin, and irinotecan- based regimens (PS)	231		New Protocol
66,279	RAD 001C	08/18/2006	PHHO2006BE00473; follow-up (PS)	228		Safety Report
66,279	RAD 001C	08/18/2006	PHHO2006DE09301; follow-up (PS)	229		Safety Report
66,279	RAD 001C	08/18/2006	PHHO2006US11747; follow-up (PS)	230		Safety Report
66,279	RAD 001C	08/17/2006	PHHO2006US11747; follow-up (PS)	227		Safety Report
66,279	RAD 001C	08/16/2006	PHHO2006BE00473 (PS)	226		Safety Report
66,279	RAD 001C	08/15/2006	PHHO2006US11747 (PS)	225		Safety Report
66,279	RAD 001C	08/04/2006	New investigator to Study CRAD001C2239 (PS)	224		New Investigator
66,279	RAD 001C	07/28/2006	Request for special protocol assessment for Study CRAD001C2240 (PS)	223		Other
66,279	RAD 001C	07/28/2006	PHHO2006DE09652; follow-up (PS)	222		Safety Report
66,279	RAD 001C	07/27/2006	Amendment No. 2 to Protocol CRAD001JC2222 (PS)	221		Change In Protocol
66,279	RAD 001C	07/26/2006	PHHO2006CA03486; follow-up (PS)	220		Safety Report
66,279	RAD 001C	07/25/2006	PHHO2006DE09859; follow-up (PS)	219		Safety Report
66,279	RAD 001C	07/21/2006	Documentation FDA position: Pediatric Exclusivity requirements NDA submission for active moiety.			Other
66,279	RAD 001C	07/21/2006	PHHO2006DE09652; follow-up (PS)	218		Safety Report
66,279	RAD 001C	07/20/2006	PHHO2006DE09652; follow-up (PS)	215		Safety Report
66,279	RAD 001C	07/20/2006	PHHO2006IT09039; follow-up (PS)	216		Safety Report

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