

16.2 Subject Data Listings

16.2.1 Discontinued Subjects

Listing 16.2.1-1 Subject Dispositions

(Page 1 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R1001	Completed	2009-09-11	194			
R1002	Completed	2009-09-16	199			
R1003	Withdrawn	2009-03-09	7	Adverse Event	Sore Gums	
R1004	Completed	2009-09-21	197			
R1005	Completed	2009-09-22	197			
R1006	Completed	2009-09-23	197			
R1007	Completed	2009-09-23	195			
R1008	Withdrawn	2009-05-28	74	Consent Withdrawn		
R1009	Withdrawn	2009-06-01	78	Consent Withdrawn		
R1010	Completed	2009-10-06	197			
R1011	Completed	2009-10-29	197			

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 2 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R1012	Completed	2009-10-29	197			
R1013	Completed	2009-11-04	197			
R1014	Withdrawn	2009-05-20	29	Lost To Follow-Up		
R1015	Completed	2009-11-10	197			
R1016	Completed	2009-11-24	194			
R1017	Completed	2009-11-20	190			
R1018	Withdrawn	2009-07-24	71	Consent Withdrawn		
R1019	Completed	2009-12-04	198			
R1020	Withdrawn	2009-11-23	173	Consent Withdrawn		
R1021	Completed	2009-12-17	197			
R1022	Completed	2009-12-30	205	Other	Subject Completed Study But Was Out Of Window	

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 3 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R1023	Withdrawn	2009-07-30	43	Consent Withdrawn		
R1024	Completed	2010-01-06	198			
R1025	Completed	2010-01-07	197			
R1026	Completed	2010-01-07	197			
R1027	Withdrawn	2009-07-28	27	Consent Withdrawn		
R1028	Completed	2010-01-29	212	Other	Subject Completed But Was Out Of Window	
R1029	Withdrawn	2009-09-21	78	Adverse Event	Vaginal Bleeding With Pregnancy	
R1030	Completed	2010-01-28	197			
R1031	Completed	2010-01-28	197			
R1032	Withdrawn	2009-11-06	113	Consent Withdrawn		
R1033	Withdrawn	2009-09-04	46	Consent Withdrawn		

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 4 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R1034	Completed	2010-02-11	197			
R1035	Completed	2010-02-11	197			
R1036	Withdrawn	2009-11-03	97	Lost To Follow-Up		
R1037	Completed	2010-02-12	197			
R2001	Withdrawn	2009-05-18	67	Consent Withdrawn		
R2002	Completed	2009-09-29	197			
R2003	Completed	2009-10-01	198			
R2004	Withdrawn	2009-05-14	53	Consent Withdrawn		
R2005	Completed	2009-10-06	197			
R2006	Withdrawn	2009-08-04	132	Consent Withdrawn		
R2007	Completed	2009-10-29	197			

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 5 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R2008	Withdrawn	2009-06-18	60	Lost To Follow-Up		
R2009	Completed	2009-11-03	197			
R2010	Completed	2009-11-04	197			
R2011	Completed	2009-11-05	197			
R2012	Completed	2009-11-09	197			
R2013	Completed	2009-11-10	197			
R2014	Completed	2009-11-16	197			
R2015	Completed	2009-11-17	197			
R2016	Completed	2009-11-20	197			
R2017	Completed	2009-11-20	197			
R2018	Withdrawn	2009-07-07	47	Consent Withdrawn		

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 6 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R2019	Completed	2009-12-08	197			
R2020	Withdrawn	2009-07-24	59	Lost To Follow-Up		
R2021	Completed	2009-12-11	190			
R2022	Completed	2010-02-11	228	Other		Subject Completed, But Was Out Of Window
R2023	Withdrawn	2009-12-22	174	Lost To Follow-Up		
R2024	Completed	2010-01-29	205	Other		Subject Completed, But Was Out Of Window
R2025	Withdrawn	2009-10-13	93	Lost To Follow-Up		
R2026	Completed	2010-01-27	198			
R2027	Completed	2010-01-27	197			
R2028	Completed	2010-02-03	197			
R2029	Completed	2010-02-04	197			

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 7 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R2030	Withdrawn	2009-09-09	43	Consent Withdrawn		
R2031	Completed	2010-02-11	196			
R2032	Withdrawn	2009-10-14	71	Lost To Follow-Up		
R3001	Completed	2009-09-14	197			
R3002	Completed	2009-09-14	197			
R3003	Completed	2009-09-15	198			
R3004	Completed	2009-09-14	197			
R3005	Withdrawn	2009-06-11	101	Consent Withdrawn		
R3006	Completed	2009-09-16	198			
R3007	Completed	2009-09-16	198			
R3008	Completed	2009-09-15	197			

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 8 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R3009	Withdrawn	2009-05-06	58	Adverse Event	Glossitis And Pharyngitis	
R3010	Completed	2009-09-22	197			
R3011	Completed	2009-10-05	195			
R3012	Withdrawn	2009-04-22	24	Adverse Event	Acne Vulgaris, Diarrhea, Dyspepsia	
R3013	Completed	2009-10-19	197			
R3014	Withdrawn	2009-07-17	102	Consent Withdrawn		
R3015	Withdrawn	2009-06-04	59	Consent Withdrawn		
R3016	Completed	2009-10-27	197			
R3017	Withdrawn	2009-05-26	42	Consent Withdrawn		
R3018	Withdrawn	2009-09-29	168	Lost To Follow-Up		
R3019	Completed	2009-11-10	197			

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 9 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R3020	Completed	2009-11-10	197			
R3021	Withdrawn	2009-06-29	56	Consent Withdrawn		
R3022	Completed	2009-11-16	196			
R3023	Withdrawn	2009-06-17	44	Consent Withdrawn		
R3024	Withdrawn	2009-06-08	28	Consent Withdrawn		
R3025	Withdrawn	2009-08-04	85	Adverse Event	Dysesthesia	
R3026	Completed	2009-11-18	190			
R3027	Withdrawn	2009-07-27	76	Lost To Follow-Up		
R3028	Completed	2009-11-23	189	Other	Subject Completed But Was Out Of Window	
R3029	Withdrawn	2009-07-23	66	Lost To Follow-Up		
R3030	Withdrawn	2009-06-09	22	Lost To Follow-Up		

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 10 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R3031	Completed	2009-11-24	190			
R3032	Withdrawn	2009-06-16	28	Consent Withdrawn		
R4001	Withdrawn	2009-06-22	113	Consent Withdrawn		
R4002	Completed	2009-09-14	197			
R4003	Completed	2009-09-15	198			
R4004	Withdrawn	2009-04-14	44	Consent Withdrawn		
R4005	Completed	2009-09-15	197			
R4006	Withdrawn	2009-04-13	34	Consent Withdrawn		
R4007	Completed	2009-09-29	203			
R4008	Completed	2009-09-23	197			
R4009	Withdrawn	2009-07-23	135	Consent Withdrawn		

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 11 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R4010	Completed	2009-09-23	197			
R4011	Completed	2009-09-23	197			
R4012	Completed	2009-09-23	197			
R4013	Withdrawn	2009-05-20	71	Consent Withdrawn		
R4014	Withdrawn	2009-07-06	118	Consent Withdrawn		
R4015	Completed	2009-09-23	197			
R4016	Completed	2009-09-25	197			
R4017	Completed	2009-09-25	197			
R4018	Completed	2009-09-25	197			
R4019	Completed	2009-10-12	197			
R4020	Completed	2009-10-12	197			

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 12 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R4021	Withdrawn	2009-07-31	124	Consent Withdrawn		
R4022	Completed	2009-10-09	194			
R4023	Completed	2009-10-12	197			
R4024	Withdrawn	2009-05-13	44	Consent Withdrawn		
R4025	Withdrawn	2009-05-15	45	Other	Did Not Like The Taste Of The Product	
R4026	Completed	2009-10-22	196			
R4027	Completed	2009-10-28	197			
R4028	Completed	2009-11-05	197			
R4029	Completed	2009-11-12	204			
R4030	Withdrawn	2009-07-07	76	Consent Withdrawn		
R4031	Withdrawn	2009-05-29	37	Consent Withdrawn		

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 13 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R4032	Completed	2009-11-05	197			
R4033	Completed	2009-11-09	197			
R4034	Withdrawn	2009-08-05	100	Consent Withdrawn		
R4035	Completed	2009-11-17	198			
R4036	Completed	2009-11-25	205	Other	Subject Completed But Was Outside Of Window	
R4037	Completed	2009-11-17	197			
R4038	Completed	2009-11-17	197			
R4039	Completed	2009-11-17	197			
R4040	Completed	2009-11-17	197			
R4041	Completed	2009-11-17	197			
R4042	Completed	2009-11-18	198			

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 14 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R4043	Withdrawn	2009-08-12	100	Consent Withdrawn		
R4044	Withdrawn	2009-07-15	72	Other	Job Transfer To Out Of Town	
R4045	Completed	2009-11-17	197			
R4046	Withdrawn	2009-10-06	153	Other	Increase In Smoking Cigarettes	
R4047	Completed	2009-12-01	203			
R4048	Withdrawn	2009-08-20	93	Consent Withdrawn		
R4049	Completed	2009-12-02	195			
R4050	Completed	2009-12-15	197			
R4051	Completed	2009-12-15	197			
R4052	Completed	2009-12-14	196			
R4053	Withdrawn	2009-08-31	91	Consent Withdrawn		

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 15 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R4054	Withdrawn	2009-11-18	168	Consent Withdrawn		
R4055	Completed	2009-12-17	197			
R4056	Withdrawn	2009-09-28	113	Consent Withdrawn		
R4057	Completed	2010-01-21	225	Other	Subject Completed But Was Out Of Window.	
R4058	Completed	2009-12-23	196			
R4059	Completed	2009-12-23	196			
R4060	Completed	2009-12-23	195			
R4061	Withdrawn	2009-08-18	62	Consent Withdrawn		
R4062	Completed	2009-12-30	196			
R4063	Completed	2009-12-30	196			
R4064	Completed	2009-12-30	196			

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 16 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R4065	Completed	2009-12-30	196			
R4066	Withdrawn	2009-09-18	93	Consent Withdrawn		
R4067	Withdrawn	2009-08-04	48	Other	Due To No Transportation	
R4068	Completed	2010-01-08	204			
R4069	Completed	2010-01-06	198			
R4070	Completed	2010-02-18	238	Other	Subject Completed But Was Out Of Window	
R4071	Completed	2010-01-08	197			
R4072	Completed	2010-01-08	197			
R4073	Withdrawn	2009-08-24	57	Other	Lost To Followup - Week 8 Visit Out Of Window	
R4074	Withdrawn	2009-08-26	59	Consent Withdrawn		
R4075	Withdrawn	2009-10-28	122	Consent Withdrawn		

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 17 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R4076	Withdrawn	2009-09-28	92	Consent Withdrawn		
R4077	Withdrawn	2009-10-19	113	Consent Withdrawn		
R4078	Withdrawn	2009-09-14	78	Consent Withdrawn		
R4079	Completed	2010-01-08	194			
R4080	Withdrawn	2009-07-28	30	Lost To Follow-Up		
R4081	Withdrawn	2009-08-10	43	Consent Withdrawn		
R4082	Withdrawn	2009-09-28	92	Consent Withdrawn		
R4083	Completed	2010-01-11	197			
R4084	Withdrawn	2009-09-11	73	Lost To Follow-Up		
R4085	Withdrawn	2009-07-30	29	Lost To Follow-Up		
R4086	Withdrawn	2009-08-13	43	Lost To Follow-Up		

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 18 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R4087	Withdrawn	2009-10-22	113	Consent Withdrawn		
R4088	Withdrawn	2009-08-27	57	Consent Withdrawn		
R4089	Withdrawn	2009-10-22	113	Consent Withdrawn		
R4090	Completed	2010-01-14	197			
R4091	Completed	2010-02-04	218	Other	Subject Completed But Was Outside The Window	
R4092	Completed	2010-01-20	203			
R4093	Completed	2010-01-28	205	Other	Subject Completed But Was Outside The Window	
R4094	Completed	2010-02-04	212	Other	Subject Completed But Was Out Of Window	
R4095	Withdrawn	2009-07-08	1	Other	Subject Incarcerated	
R4096	Completed	2010-02-23	231	Other	Subject Completed But Outside The Window	
R4097	Completed	2010-01-20	197			

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 19 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R4098	Withdrawn	2009-10-12	97	Consent Withdrawn		
R4099	Completed	2010-02-02	210	Other	Subject Completed But Was Out Of Window	
R4100	Completed	2010-01-20	197			
R4101	Withdrawn	2009-08-05	29	Lost To Follow-Up		
R4102	Completed	2010-01-20	197			
R4103	Withdrawn	2009-08-24	46	Consent Withdrawn		
R4104	Withdrawn	2009-08-14	29	Lost To Follow-Up		
R4105	Completed	2010-02-04	197			
R4106	Withdrawn	2009-10-22	92	Consent Withdrawn		
R4107	Completed	2010-02-04	197			
R4108	Withdrawn	2009-09-28	68	Consent Withdrawn		

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 20 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R4109	Withdrawn	2009-09-15	55	Other	Discontinued Due To Noncompliance-Would Not Return Phone Calls	
R4110	Withdrawn	2009-08-28	37	Consent Withdrawn		
R4111	Withdrawn	2009-07-30	8	Lost To Follow-Up		
R4112	Withdrawn	2009-09-23	63	Consent Withdrawn		
R4113	Completed	2010-02-04	197			
R4114	Completed	2010-02-04	197			
R4115	Withdrawn	2009-10-22	92	Lost To Follow-Up		
R4116	Completed	2010-02-04	197			
R4117	Completed	2010-02-04	197			
R4118	Completed	2010-02-04	197			
R4119	Completed	2010-02-16	209	Other	Subject Completed But Outside The Window	

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 21 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R4120	Completed	2010-02-05	198			
R4121	Withdrawn	2009-08-27	29	Lost To Follow-Up		
R5001	Completed	2010-01-11	196			
R5002	Completed	2010-01-11	196			
R5003	Completed	2010-01-11	196			
R5004	Completed	2010-01-18	197			
R5005	Withdrawn	2009-10-05	92	Lost To Follow-Up		
R5006	Completed	2010-01-18	197			
R5007	Withdrawn	2009-07-06	1	Lost To Follow-Up		
R5008	Completed	2010-01-18	196			
R5009	Withdrawn	2009-08-03	28	Terminated By Sponsor		

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 22 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R5010	Withdrawn	2009-09-08	64	Consent Withdrawn		
R5011	Completed	2010-01-18	196			
R5012	Withdrawn	2009-11-11	125	Consent Withdrawn		
R5013	Completed	2010-01-27	199			
R5014	Withdrawn	2009-11-13	123	Consent Withdrawn		
R5015	Completed	2010-01-25	196			
R5016	Withdrawn	2009-11-09	116	Consent Withdrawn		
R5017	Withdrawn	2009-12-21	158	Consent Withdrawn		
R5018	Completed	2010-02-01	200			
R5019	Completed	2010-02-01	196			
R5020	Completed	2010-02-01	196			

^a Study Day is relative to the date of first study product administration (Day 1).

Listing 16.2.1-1 Subject Dispositions

(Page 23 of 23)

Study Population: ITT

Subject Number	Completed/ Withdrawn	Date	Study Day ^a	Reason, if Withdrawn	Specify	Investigator Comments
R5021	Completed	2010-02-02	197			
R5022	Completed	2010-02-08	200			
R5023	Completed	2010-02-08	200			
R5024	Withdrawn	2009-08-24	28	Lost To Follow-Up		
R5025	Completed	2010-02-08	196			
R5026	Withdrawn	2009-07-28	1	Lost To Follow-Up		
R5027	Withdrawn	2010-02-19	207	Adverse Event	Pregnancy	
R5028	Completed	2010-02-19	206	Other	Subject Completed But Was Out Of Window.	

^a Study Day is relative to the date of first study product administration (Day 1).