



Common Drug Review *

Submission Status

Product: Sutent
Generic Name: sunitinib malate
Manufacturer: Pfizer Canada Inc.
Submission Type: Resubmission
Date Submission Received: 2006-Sep-20 **Date NOC Issued:** 2006-Aug-17
Targeted CEDAC Meeting: 2007-Jan-17 **Priority Review Granted:** Denied

Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments	
1	Submission Deemed Complete	5	2006-Sep-27	2006-Sep-27	Priority review denied October 11, 2006.
2	CDR Reviewers' Reports Completed <ul style="list-style-type: none"> • Reviewers selected and contracted • Literature search and selection completed • Systematic review of clinical data completed • Critical appraisal of pharmacoeconomic (PE) data completed • Clinical and PE reports written • Reports edited and finalized • Reviewers' reports sent to manufacturer 	45	2006-Nov-29	2006-Nov-28	Additional information requested September 27, 2006. Additional information received September 28, 2006. Additional information requested October 11, 2006. Additional information received October 12, 2006. Additional information requested October 31, 2006. Additional information received November 8, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Dec-08	2006-Dec-08	Due date for manufacturer's comments December 7, 2006.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Dec-19	2006-Dec-19	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2007-Jan-03	2007-Jan-03	
6	CEDAC Meeting		2007-Feb-21	2007-Feb-21	At the January 17, 2007, CEDAC meeting Recommendation deferred to February 21, 2007 CEDAC meeting.
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2007-Feb-28	2007-Feb-28	
8	Embargo Period*** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation and Reasons for Recommendation	10	2007-Mar-14	2007-Mar-14	Request for Reconsideration received March 14, 2007.
9 (a)	Final Recommendation sent to Drug Plans, ACP, and Manufacturer (No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved)	5			
OR					
9 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
OR					
9 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2007-Apr-18	2007-Apr-18	
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2007-Apr-25	2007-Apr-26	Notice of Final Recommendation issued.

* Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.cadth.ca for more details.

** The CDR review process is initiated AFTER a submission is deemed complete. The target dates for this report are based on the CEDAC meeting schedule, which is posted on www.cadth.ca.

*** The Recommendation and Reasons for Recommendation are to be held in confidence and not acted upon until after the CDR Directorate has issued the notice of Final Recommendation.

****Reflects updates as of Thursday noon.