Common Drug Review *

Submission Status

Product: Nexavar
Generic Name: sorafenib
Manufacturer: Bayer Inc.
Submission Type: NEW
Date Submission Received: 2006-Jul-31
Date NOC Issued: 2006-Jul-28
Targeted CEDAC Meeting: 2006-Nov-22
Priority Review Granted: Granted

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2006-Aug-06	2006-Aug-02	Priority Review granted August 8, 2006.
2	CDR Reviewers' Reports Completed • 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-Oct-06	2006-Oct-04	Additional information requested August 3, 2006. Additional information received August 10, 2006. Additional information requested August 22, 2006. Additional information received August 29, 2006. Additional information requested August 30, 2006. Additional information received September 6, 2006. Additional information requested September 14, 2006. Target CEDAC meeting updated due to change in November meeting date. Additional information received September 18, 2006. Additional information received September 20, 2006. Additional information requested September 22, 2006. Additional information received September 25, 2006. Additional information requested October 12, 2006. Additional information received October 18, 2006. Additional information requested October 19, 2006. Additional information received October 19, 2006. Additional information received October 20, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Oct-18	2006-Oct-16	Due date for manufacturer's comments is October 16, 2006.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Oct-27	2006-Oct-25	Due date for reviewers' response is October 25, 2006.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Nov-08	2006-Nov-08	
6	CEDAC Meeting		2006-Nov-22	2006-Nov-22	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Nov-29	2006-Nov-29	
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	2006-Dec-13	2006-Dec-13	Request for Reconsideration received December 13, 2006.
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-Feb-21	2007-Feb-21	January 17, 2007, CEDAC Recommendation deferred to February 21, 2007 CEDAC meeting.
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2007-Feb-28	2007-Feb-28	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.