Common Drug Review *

Submission Status

Product: Raptiva
Generic Name: efalizumab
Manufacturer: Serono Canada Inc.
Submission Type: New
Date Submission Received: 2005-Oct-25
Date NOC Issued: 2005-Oct-24
Targeted CEDAC Meeting: 2006-Apr-19
Priority Review Granted: Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2005-Nov-01	2005-Oct-31	
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-Jan-09	2006-Feb-15	Additional information requested November 23, 2005. Additional information received November 24, 2005. Additional information requested December 2 & 6 2005. Additional information received December 5, 6, 7, 8, 9, 14 & 19, 2005. Additional information requested January 16, 2006. Additional information received January 20, 2006. New due date for Reviewer's Reports to be determined after assessment of additional info. New due date for Reviewer's Reports to manufacturer is February 15, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Feb-24	2006-Feb-24	Rescheduled to the April 19, 2006 CEDAC meeting due to volume of information received from the manufacturer. New due date for Manufacturer's Comments is February 24, 2006.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Mar-07	2006-Mar-07	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Apr-05	2006-Apr-05	
6	CEDAC Meeting		2006-Apr-19	2006-Apr-19	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Apr-26	2006-Apr-26	
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-May-10	2006-May-10	Request for reconsideration received May 10, 2006. Final recommendation discussed at July 26, 2006 CEDAC meeting. Embargoed Final Recommendation released August 2, 2006. Opportunity to request clarification due August 17, 2006. New due date for Final Recommendation is August 24, 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	2006-Jul-26	2006-Jul-26	Discussed at June 21, 2006 CEDAC. Notice of final recommendation delayed. CEDAC to further discuss final recommendation at July 26, 2006 meeting.
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2006-Aug-24	2006-Aug-24	

* 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.