Common Drug Review *

Submission Status

Product: Baraclude
Generic Name: entecavir
Manufacturer: Bristol-Myers Squibb Canada
Submission Type: New
Date Submission Received: 2006-Dec-12
Date NOC Issued: 2006-June-16
Targeted CEDAC Meeting: 2007-May-16
Priority Review Granted: Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Assessment	5	2006-Dec-19	2006-Dec-20	Submission deemed incomplete. Additional requirements requested December 20, 2006.
	Submission deemed complete			2006-Dec-21	Additional requirements received December 21, 2006. Submission deemed complete. Submission placed in queue in accordance with CDR procedures. Review to be initiated pending the availability of resources. Review initiated January 30, 2007.
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	2007-Mar-29	2007-Mar-29	Additional information requested January 25, 2007. Additional information received January 31, 2007. Additional information requested February 19, 2007. Additional information received February 22, 2007. Additional information requested March 1, 2007. Additional information requested March 7, 2007. Additional information received March 8, 2007. Additional information received March 9, 2007.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2007-Apr-10	2007-Apr-10	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2007-Apr-19	2007-Apr-19	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2007-May-02	2007-May-02	
6	CEDAC Meeting		2007-Sep-19	2007-Sep-19	Discussed at May 16, 2007 CEDAC meeting. Recommendation deferred to the June 20, 2007 CEDAC meeting. Discussed at the June 20, 2007 CEDAC meeting. Recommendation deferred to September 19, 2007 CEDAC meeting.
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2007-Sep-26	2007-Sep-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	2007-Oct-11	2007-Oct-12	Request for extension of Embargo Period received. Extension to October 12, 2007 granted. Request for Reconsideration received October 12, 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-Nov-21	2007-Nov-21	
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2007-Nov-28	2007-Nov-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.
Reflects updates as of Thursday noon.