Common Drug Review *

Submission Status

Product: Lucentis

Generic Name: ranibizumab

Manufacturer: Novartis Pharmaceuticals Inc.

Submission Type: New

Date Submission Received: 2007-Jul-12 **Date NOC Issued:** 2007-June-26

Targeted CEDAC Meeting: 2007-Nov-21 **Priority Review Granted:** Denied

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Assessment	5	2007-Jul-19	2007-Jul-19	Submission material filed with CDR pre NOC through collaboration with Health Canada and the manufacturer. Due to confidentiality, first CDR web report posted July 20, 2007. Priority Review requested. Priority Review request denied July 25, 2007.
	Submission deemed complete			2007-Jul-19	Submission deemed complete.
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-Oct-04	2007-Sep-26	Information received from Health Canada prior to June 26, 2007. Information received from manufacturer prior to June 26, 2007. Additional information requested July 24, 2007. Additional information requested July 31, 2007. Additional information received August 1, 2007. Additional information received August 13, 2007. Additional information requested August 16, 2007. Additional information received August 21, 2007. Additional information requested September 10, 2007. Additional information received September 11, 2007. Response to request for additional information received September 18, 2007.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2007-Oct-16	2007-Oct-05	Due date for manufacturer's comments October 5, 2007.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2007-Oct-25	2007-Oct-17	Due date for reviewers' reply to manufacturer's comments October 17, 2007.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2007-Nov-07	2007-Nov-07	
6	CEDAC Meeting		2007-Nov-21	2007-Nov-21	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2007-Nov-28	2007-Nov-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-Dec-12	2007-Dec-12	Request for Reconsideration received December 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	2008-Mar-19	2008-Mar-19	Discussed at January 23, 2008 CEDAC meeting. Recommendation deferred pending further discussion at the March 19, 2008 CEDAC meeting.
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2008-Mar-27		

* 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.