Common Drug Review *

Submission Status

Product: Levemir
Generic Name: insulin detemir
Manufacturer: Novo Nordisk Canada Inc.
Submission Type: New
Date Submission Received: 2005-Dec-19
Date NOC Issued: 2005-Sep-29
Targeted CEDAC Meeting: 2006-May-17
Priority Review Granted: Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2006-Jan-03	2006-Jan-04	Submission incomplete - Missing information requested January 3, 2006. Requested information received January 4, 2006. 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	2006-Mar-08	2006-Mar-10	Additional information requested January 23, 2006. Additional information received February 6, 2006. Additional information requested February 10, 2006. Additional information requested February 13, 2006. Additional information received February 17, 2006. Additional information requested February 17, 2006. Additional information received February 20, 2006. Additional information received February 24, 2006. Additional information received February 28, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Apr-17	2006-Apr-17	New date for Manufacturer's comments March 20, 2006. Request for extension received March 13, 2006. Extension granted, due date for manufacturer's comments April 17, 2006. Rescheduled to May 17, 2006 CEDAC meeting due to extension provided to manufacturer.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Apr-26	2006-Apr-26	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-May-03	2006-May-03	
6	CEDAC Meeting		2006-May-17	2006-May-17	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-May-25	2006-May-25	
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-Jun-08	2006-Jun-14	Request for extension of Embargo Period received on June 1, 2006. Extension approved, new end date for Embargo Period is June 14, 2006. Request for reconsideration received June 14, 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	
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2006-Aug-02	2006-Aug-02	

* 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.