Common Drug Review *

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product: Lantus
Generic Name: insulin glargine (rDNA origin)
Manufacturer: Sanofi-Aventis Canada Inc.
Submission Type: Resubmission
Date Submission Received: 2006-Mar-27
Date NOC Issued: 2002-Apr-03
Targeted CEDAC Meeting: 2006-Jul-26
Priority Review Granted: Not requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2006-Apr-03	2006-Apr-03	
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-Jun-07	2006-Jun-14	Additional requirements requested April 20, 2006. Additional information requested April 28, 2006. Additional information received May 8, 2006. Additional requirements received on May 15, 2006. Additional information requested May 17, 2006. Additional information requested May 19, 2006. Additional information received May 23, 2006. Additional information requested May 26, 2006. Additional information received June 1, 2006. Additional information requested June 1, 2006. Additional information received June 2, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Jun-16	2006-Jun-22	Due date for Manufacturer's comments June 23, 2006.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Jun-27	2006-Jun-28	Due date for reviewers' reply July 4, 2006.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Jul-12	2006-Jul-12	
6	CEDAC Meeting		2006-Jul-26	2006-Jul-26	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Aug-02	2006-Aug-02	
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-Aug-17	2006-Sep-15	Manufacturer requested extension of Embargo Period to September 15, 2006. Request granted. Request for reconsideration received September 15, 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-Oct-18	2006-Oct-18	
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2006-Oct-25	2006-Oct-25	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.