## **Common Drug Review \***



**Submission Status** 

Product: Forteo

**Date NOC Issued:** 

2004-Jun-03

Generic Name: teriparatide (rDNA origin) injection Manufacturer: Eli Lilly Canada Inc.

Submission Type: Resubmission #1

Date Submission Received: 2009-May-29

**Targeted CEDAC Meeting: Priority Review Granted:** Not Requested

Targeted OLDAC Meeting.			Thomas Review Granted.		Not Requested
Phase		Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission deemed complete	5	2006-Jun-05	N/A	Additional information requested on June 15, 2006. Additional information received on July 11, 2006. Withdrawn at request of manufacturer, August 4, 2006.
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		N/A	
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7		N/A	
4	Reviewers' Reply to Manufacturer's Comments Completed	7		N/A	
5	CEDAC Brief Completed and Sent to CEDAC Members	5		N/A	
6	CEDAC Meeting				
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5			
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			
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			
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5			

<sup>\*</sup> Refer to the Procedure for Common Drug Review on the Common Drug Review section of <a href="www.cadth.cg">www.cadth.cg</a> 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.