Common Drug Review *



Submission Status

Product: Azilect

Generic Name: rasagiline mesylate Manufacturer: Teva Pharmaceuticals Industries Ltd.

Submission Type: Request for Advice

Date Submission Received: 2009-Mar-10

Date NOC Issued: 2006-Aug-17

Targeted CEDAC Meeting: 2009-Sep-16

Priority Review Granted: Not Requested

	Targeted CEDAC Meeting:	2009-Sep-16	Priority R	eview Granted:	Not Requested
	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	CDR Request for Advice Assessment - Review team formed and determines approach for responding to Request for Advice	10	2009-Mar-24		ACP Request for Advice
2	CDR Reviewers' reports or other document completed as determined by CDR team i) Reviewers' Report sent to Manufacturer for comment ii) Documentation completed as required and sent to manufacturer for information only. (no comments required)	45	2009-Jun-02	2009-May-01	Additional information requested March 13, 2009. Additional information received March 17, 2009.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2009-Jun-11	2009-May-11	Due date for manufacturer's comments May 12, 2009.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2009-Jun-22	2009-May-21	Due date for reviewers' reply May 21, 2009.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2009-Jun-03	2009-Jun-03	
6	CEDAC Meeting		2009-Jun-17	2009-Jun-17	CEDAC meeting date changed from September 16, 2009 to June 17, 2009.
7	Recommendation and Reasons for Recommendation or Response to Request for Advice sent to Drug Plans, ACP and Manufacturer	5	2009-Jun-24	2009-Jun-24	Response to Request for Advice sent to Drug Plans, ACP and Manufacturer on June 24, 2009. No CEDAC recommendation issued in response to this Request for Advice.
8 (a)	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	2009-Jul-09		
	OR				
8 (b)	No Embargo Period if Request for Advice does not result in a Revised Recommendation or Reasons for Recommendation				
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			

Reflects updates as of Thursday noon.

^{*} 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 submission is assessed. 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.