Common Drug Review *



Submission Status

ency for	Product:	Finacea						
innologies	Generic Name:	azelaic acid						
	Manufacturer:	Bayer Inc.						
Indication:		Rosacea						
Submission Type:		Initial						
Date Submission Received:		2010-Aug-31	Date NOC Issued:	2007-Mar-27				
Targeted CEDAC Meeting:		2011-Jan-19	Priority Review Granted:	Not Requested				
		Target	Toward Actual					

Phase		Target Time (Business Days)	Target Date**	Actual CDR Date	Comments		
1	Submission deemed complete	5	2010-Sep-08	2010-Sep-08	Submission deemed complete.		
2	Patient group input submission received		2010-Sep-22	2010-Sep-22	Patient group input received.		
3	CADTH Reviewers' Reports sent to Manufacturer	45	2010-Nov-23	2010-Nov-23			
4	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2010-Dec-02	2010-Dec-02			
5	CEDAC Meeting		2011-Jan-19	2011-Jan-19			
6	CEDAC Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2011-Jan-26	2011-Jan-26			
7	Embargo Period*** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2011-Feb-09	2011-Feb-07			
8 (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	2011-Feb-16	2011-Feb-16	Notice of Final Recommendation.		
OR .							
8 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5					
OR							
8 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates					
9	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5					

 $^{^{*}\ \}text{Refer to the Procedure for Common Drug Review on the Common Drug Review section of } \underline{\text{www.cadth.ca}}\ \text{for more details.}$

^{**} The Formulary 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 ways cadth ca

www.cadth.ca.

*** The Recommendation is held in confidence and not acted upon until after CADTH has issued the notice of Final Recommendation.

Reflects updates as of Thursday noon.