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Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Common Drug Review *

Submission Review Status

Product: Replagal

Generic Name: agalsidase alfa

Manufacturer: Transkaryotic Therapies Inc.

Submission Type: NEW

Priority Review: Approved

Date NOC Issued: 2004-Feb-06

Date Submission Received: 2004-Feb-19

Date Submission Deemed Complete (Category 1): 2004-Feb-23

	Task	Time frame (Business Days)	Target Date**	Actual CDR Date	Total Time (Business Days)	Comments
1	Check Submission Completeness	5	2004-Feb-26	2004-Feb-23	2	Priority review approved Feb. 23/04
2	Assign Submission Coordinator, Contract Reviewers	10	2004-Mar-08	2004-Mar-04	8	
3	Search and Retrieve Literature	10	2004-Mar-22	2004-Mar-19	11	Additional information requested on April 6, 2004. Additional information received April 14, 2004.
4	Undertake Review and Prepare Report	20	2004-Apr-20	2004-Apr-26	25	
5	Conduct Quality Assessment of Reviewers' Reports	5	2004-Apr-27	2004-May-04	6	
6	Comment on Reviewers' Reports **(Manufacturer's Task)**	7	2004-May-06	2004-May-14	8	
7	Reply to Manufacturer's Comments **(Reviewer's Task)**	7	2004-May-17	2004-May-26	7	
8	Prepare CEDAC Brief	5	2004-May-25	2004-May-31	3	
9	Start review by CEDAC Members	10	2004-Jun-08	2004-Jun-03	33	
10	CEDAC Meeting		2004-Jun-16	2004-Jun-16	1	Deferred to July 21, 2004 CEDAC meeting.
			2004-Jul-21	2004-Jul-21		
11	Send CEDAC Recommendation and Reasons for Recommendation	5	2004-Jul-28	2004-Jul-28		
12	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	2004-Aug-12	2004-Aug-12		Request for Reconsideration received August 12, 2004.
13(a)	Final Recommendation sent to Drug Plans, CDRC, and Manufacturer (No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved)	5				
	OR					
13(b)	Clarification and Final Recommendation sent to Drug Plans, CDRC, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5				
	OR					
13(c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2004-Nov-17	2004-Nov-17	1	The CDR procedure for Replagal was put on hold, pending examination of issues raised by the manufacturer Fabrazyme. CCOHTA gave Transkaryotic Therapies Inc, this option to ensure both drug reviews were treated consistently. October 28, 2004 hold was lifted and reconsideration scheduled.
14	Final Recommendation sent to Drug Plans, CDRC, and Manufacturer	5 Following CEDAC Meeting	2004-Nov-24	2004-Nov-24		Notice of Final Recommendation Issued.

* Refer to CDR Procedures for detailed steps at http://www.ccohta.ca **Tasks 2-9 are initiated AFTER submission is deemed complete.

*** 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.