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Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Common Drug Review *

Submission Review Status

Product: Evra

Generic Name: norelgestromin 6.0mg/ethinyl estradiol 0.60mg

Manufacturer: Janssen-Ortho

Submission Type: NEW

Priority Review:

Date NOC Issued: 2003-Nov-19

Date Submission Received: 2003-Dec-19

Date Submission Deemed Complete (Category 1): 2003-Dec-23

	Task	Time frame (Business Days)	Target Date**	Actual CDR Date	Total Time (Business Days)	Comments
1	Check Submission Completeness	5	2004-Jan-06	2003-Dec-23	2	
2	Assign Submission Coordinator, Contract Reviewers	10	2004-Jan-15	2004-Jan-13	8	
3	Search and Retrieve Literature	10	2004-Jan-29	2004-Feb-04	16	
4	Undertake Review and Prepare Report	20	2004-Feb-26	2004-Mar-04	21	
5	Conduct Quality Assessment of Reviewers' Reports	5	2004-Mar-04	2004-Mar-17	9	
6	Comment on Reviewers' Reports **(Manufacturer's Task)**	7	2004-Mar-15	2004-Mar-26	7	
7	Reply to Manufacturer's Comments **(Reviewer's Task)**	7	2004-Mar-24	2004-Apr-06	7	
8	Prepare CEDAC Brief	5	2004-Mar-31	2004-Apr-12	3	
9	Start review by CEDAC Members	10	2004-Apr-15	2004-Apr-14	10	
10	CEDAC Meeting		2004-Apr-28	2004-Apr-28	1	
11	Send CEDAC Recommendation and Reasons for Recommendation	5	2004-May-05	2004-May-05	5	
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-May-19	2004-May-19	10	Request for Reconsideration received.
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-Jun-16	2004-Jun-16	1	Request for Reconsideration granted. Reconsideration placed on next CEDAC agenda.
14	Final Recommendation sent to Drug Plans, CDRC, and Manufacturer	5 Following CEDAC Meeting	2004-Jun-23	2004-Jun-23		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.