# Common Drug Review *

## Submission Status

**Product:** Fosavance

**Generic Name:** alendronate sodium /cholecalciferol

**Manufacturer:** Merck Frosst Canada Ltd.

**Submission Type:** New

**Date Submission Received:** 2006-Mar-27 **Date NOC Issued:** 2006-Feb-03

**Targeted CEDAC Meeting:** 2006-Jul-26 **Priority Review Granted:** Not requested

| | Phase | Target Time (Business Days) | Target Date** | Actual CDR Date | Comments |
|---|---|---|---|---|---|
| 1 | Submission Deemed Complete | 5 | 2006-Apr-03 | 2006-Apr-03 | |
| 2 | CDR Reviewers' Reports Completed<br>• Reviewers selected and contracted<br>• Literature search and selection completed<br>• Systematic review of clinical data completed<br>• Critical appraisal of pharmacoeconomic (PE) data completed<br>• Clinical and PE reports written<br>• Reports edited and finalized<br>• Reviewers' reports sent to manufacturer | 45 | 2006-Jun-07 | 2006-Jun-02 | Clarification requested May 23, 2006.<br>Clarification received May 26, 2006. |
| 3 | Comments from Manufacturer on Reviewers' Reports Received by CDR | 7 | 2006-Jun-16 | 2006-Jun-13 | Due date for manufacturer's comments June 13, 2006. |
| 4 | Reviewers' Reply to Manufacturer's Comments Completed | 7 | 2006-Jun-27 | 2006-Jun-21 | Due date for Reviewer's Reply June 22, 2006. |
| 5 | CEDAC Brief Completed and Sent to CEDAC Members | 5 | 2006-Jul-12 | 2006-Jul-12 | |
| 6 | CEDAC Meeting | | 2006-Jul-26 | 2006-Jul-26 | |
| 7 | CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer | 5 | 2006-Aug-02 | 2006-Aug-02 | |
| 8 | Embargo Period***<br>Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation and Reasons for Recommendation | 10 | 2006-Aug-17 | 2006-Aug-23 | Manufacturer requested extension of Embargo Period to August 23, 2006. Request granted.<br>Request for Reconsideration received August 22, 2006. |
| 9 (a) | Final Recommendation sent to Drug Plans, ACP, and Manufacturer<br>(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<br>(Clarification Requested, no Request for Reconsideration made) | 5 | | | |
| | **OR** | | | | |
| 9 (c) | Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request) | 25<br>Depends on Meeting Dates | 2006-Sep-20 | 2006-Sep-20 | |
| 10 | Final Recommendation sent to Drug Plans, ACP, and Manufacturer | 5 | 2006-Sep-27 | 2006-Sep-27 | Notice of Final Recommendation issued. |

* 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 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.