### Product Details
- **Product:** Fabrazyme (AGALSIDASE BETA)
- **Generic Name:** Agalsidase beta
- **Manufacturer:** Genzyme Canada

### Submission Details
- **Date Submission Received:** 2004-Dec-10
- **Date NOC Issued:** 2004-Jan-23
- **Targeted CEDAC Meeting:** 2005-Apr-20
- **Priority Review Granted:** Not Requested

### Submission Status

<table>
<thead>
<tr>
<th>Phase</th>
<th>Target Time (Business Days)</th>
<th>Target Date**</th>
<th>Actual CDR Date</th>
<th>Comments</th>
</tr>
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<tr>
<td>1</td>
<td>Submission Deemed Complete</td>
<td>5</td>
<td>2004-Dec-17</td>
<td>2004-Dec-17</td>
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</table>
| 2     | CDR Reviewers' Reports Completed  
• Reviewers selected and contracted  
• Literature search and selection completed  
• Systematic review of clinical data completed  
• Critical appraisal of pharmacoeconomic (PE) data completed  
• Clinical and PE reports written  
• Reports edited and finalized  
| 3     | Comments from Manufacturer on Reviewers' Reports Received by CDR | 7 | 2005-Mar-09 | 2005-Mar-23 | Due date for manufacturer's comments March 15, 2005. Extension granted, due date for manufacturer's comments March 22, 2005. |
| 5     | CEDAC Brief Completed and Sent to CEDAC Members | 5 | 2005-Apr-06 | 2005-Apr-08 |
| 6     | CEDAC Meeting | | 2005-Apr-20 | 2005-Apr-20 |
| 7     | CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer | 5 | 2005-Apr-27 | 2005-Apr-27 |
| 8     | 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 | 2005-May-11 | 2005-May-12 |
| 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 | 2005-May-18 | Notice of Final Recommendation issued. |
| 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  
(After Manufacturer's request) | 25 | Depends on Meeting Dates | |
| 10 | Final Recommendation sent to Drug Plans, ACP, and Manufacturer | | 5 |


** 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.ccohta.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.