# Common Drug Review *

## Submission Status

Canadian Agency for Drugs and Technologies in Health

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| **Product:** | Vantas |
| **Generic Name:** | histrelin acetate |
| **Manufacturer:** | Paladin Labs Inc. |
| **Submission Type:** | New |
| **Date Submission Received:** | 2006-Sep-20 |
| **Date NOC Issued:** | 2006-Mar-10 |
| **Targeted CEDAC Meeting:** | 2007-Feb-21 |
| **Priority Review Granted:** | Not requested |

| | Phase | Target Time (Business Days) | Target Date** | Actual CDR Date | Comments |
|---|---|---|---|---|---|
| 1 | Submission Deemed Complete | 5 | 2006-Sep-27 | 2006-Oct-04 | Submission incomplete - missing information requested September 27, 2006.<br>Required information received September 29, 2006.<br>Required information received October 4, 2006.<br>Category 1 requirements deemed complete October 4, 2006.<br>Category 2 requirements incomplete - Required information requested October 4, 2006.<br>Required information received October 10, 2006.<br>Category 2 requirements deemed complete October 10, 2006. |
| 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-Dec-15 | 2006-Dec-15 | Additional information requested November 16, 2006.<br>Additional information received November 21, 2006.<br>Additional information requested November 23, 2006.<br>Additional information received November 30, 2006. |
| 3 | Comments from Manufacturer on Reviewers' Reports Received by CDR | 7 | 2007-Jan-03 | 2007-Jan-03 | |
| 4 | Reviewers' Reply to Manufacturer's Comments Completed | 7 | 2007-Jan-12 | 2007-Jan-12 | |
| 5 | CEDAC Brief Completed and Sent to CEDAC Members | 5 | 2007-Feb-07 | 2007-Feb-07 | |
| 6 | CEDAC Meeting | | 2007-Feb-21 | 2007-Feb-21 | |
| 7 | CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer | 5 | 2007-Feb-28 | 2007-Feb-28 | |
| 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 | 2007-Mar-14 | 2007-Mar-14 | Request for Reconsideration received March 14, 2007. |
| 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 | 2007-Apr-18 | 2007-Apr-18 | |
| 10 | Final Recommendation sent to Drug Plans, ACP, and Manufacturer | 5 | 2007-Apr-25 | 2007-Apr-26 | 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.
****Reflects updates as of Thursday noon.