## Common Drug Review *

**Submission Status**

**Product:** Lucentis  
**Generic Name:** ranibizumab  
**Manufacturer:** Novartis Pharmaceuticals Inc.  
**Submission Type:** New

<table>
<thead>
<tr>
<th>Date Submission Received</th>
<th>Date NOC Issued</th>
<th>Targeted CEDAC Meeting</th>
<th>Priority Review Granted</th>
<th>Comments</th>
</tr>
</thead>
</table>

### Phase 1: Submission Assessment

- **Target Time (Business Days):** 5  
- **Target Date** 2007-Jul-19  
- **Actual CDR Date** 2007-Jul-19  

### Phase 2: CDR Reviewers’ Reports Completed

- **Target Time (Business Days):** 45  
- **Target Date** 2007-Oct-04  
- **Actual CDR Date** 2007-Sep-26  

### Phase 3: Comments from Manufacturer on Reviewers’ Reports Received by CDR

- **Target Time (Business Days):** 7  
- **Target Date** 2007-Oct-16  
- **Actual CDR Date** 2007-Oct-05  
- **Comments:** Due date for manufacturer's comments October 5, 2007.

### Phase 4: Reviewers’ Reply to Manufacturer’s Comments Completed

- **Target Time (Business Days):** 7  
- **Target Date** 2007-Oct-25  
- **Actual CDR Date** 2007-Oct-17  
- **Comments:** Due date for reviewers’ reply to manufacturer’s comments October 17, 2007.

### Phase 5: CEDAC Brief Completed and Sent to CEDAC Members

- **Target Time (Business Days):** 5  
- **Target Date** 2007-Nov-07  
- **Actual CDR Date** 2007-Nov-07  
- **Comments:**

### Phase 6: CEDAC Meeting

- **Target Time (Business Days):**  
- **Target Date** 2007-Nov-21  
- **Actual CDR Date** 2007-Nov-21  
- **Comments:**

### Phase 7: CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer

- **Target Time (Business Days):** 5  
- **Target Date** 2007-Nov-28  
- **Actual CDR Date** 2007-Nov-28  
- **Comments:**

### Phase 8: Embargo Period***

- **Target Time (Business Days):** 10  
- **Target Date** 2007-Dec-12  
- **Actual CDR Date** 2007-Dec-12  
- **Comments:** Request for Reconsideration received December 12, 2007.

### Phase 9 (a): Final Recommendation sent to Drug Plans, ACP, and Manufacturer (No Requests for Clarification are made AND no Request for Reconsideration is made)

- **Target Time (Business Days):** 5  
- **Target Date** 2007-Dec-12  
- **Actual CDR Date** 2007-Dec-12  
- **Comments:**

### OR

- **Phase 9 (b): Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)

- **Target Time (Business Days):** 5  
- **Target Date** 2008-Mar-19  
- **Actual CDR Date** 2008-Mar-19  
- **Comments:** Discussed at January 23, 2008 CEDAC meeting. Recommendation deferred pending further discussion at the March 19, 2008 CEDAC meeting.

### OR

- **Phase 9 (c): Placed on CEDAC Agenda For Reconsideration (At Manufacturer’s request)

- **Target Time (Business Days):** 25  
- **Target Date** Depends on Meeting Dates  
- **Actual CDR Date** 2008-Mar-19  
- **Comments:**

- **Phase 10: Final Recommendation sent to Drug Plans, ACP, and Manufacturer

- **Target Time (Business Days):** 5  
- **Target Date** 2008-Mar-27  
- **Actual CDR Date** 2008-Mar-27  

---

* 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.

March 20, 2008