



Mid-Cycle Committee Meeting

STN Number:	125296/0
Manufacturer:	Duramed Research, Inc.
Product:	Adenovirus Type 4 and Type 7 Vaccines, Live, Oral

Date: February 27, 2009
To: BLA 125296/0 File
From: Committee Chairperson
Type: Mid-Cycle Committee Meeting

Duramed Research, Inc. submitted a Biologics License Application (BLA) for approval of Adenovirus Type 4 and Type 7 Vaccines, Live, Oral on September 30, 2008. The purpose of the mid-cycle meeting is to discuss review progress, upcoming review milestones and any issues which may impact the review process or the approval of the BLA.

Mid-Cycle Review Updates:

1. Product (CMC)

A new Product Reviewer has been assigned to the BLA due to workload redistribution within the Product office. DVP and DPQ have discussed the product testing plan and protocol for lot release to decide what tests should be performed. DVP will provide a list of any issues identified to the committee chair as soon as possible.

2. Clinical (including labeling & PREA)

The draft clinical review has been forwarded to the committee chair for review. The PeRC meeting has been scheduled for May 13, 2009. A request for a full pediatric waiver will be requested.

3. Statistics

The Statistician has completed some calculations on the clinical data provided and it appears the Sponsor may have met their statistical end point for efficacy.

4. Pharmacovigilance (PMC/REMS)

The design of the post-marketing risk management plan is acceptable although it is lacking in detail. Additional details to be requested from the Sponsor will be sent to the committee chair in the next couple of weeks.

5. BioResearch Monitoring (Inspections)

Inspections of the clinical sites have been completed and the establishment inspection reports (EIR) should be completed by the end of March or early April.

6. Facility (inspections)

Inspection of the manufacturing facility in --(b)(4)-- has been completed and the EIR should be completed by mid to late March. The facility inspection in Forest, Virginia is scheduled

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for the week of April 20, 2009 and the EIR should be completed by mid May. Further clarification of the lyophilization and manufacturing process will be requested from the Sponsor within the next two weeks.

7. Lot Release/Testing Plan

DPQ is continuing to develop the lot release testing plan and protocol. A list of items needed from the Sponsor for testing will be sent to the committee chair within the next two weeks. The product testing plan will be completed by the end of March.

8. Advertising and Promotional Labeling

The new request for proprietary name review to replace the original requested name has been received. Upon cursory review, the two new trade names requested may not be acceptable either. The sponsor will be contacted to discuss options, including having no proprietary name, considering that the vaccine is intended for military use only.

9. Other Discussion Items

- It has been determined by senior management that a VRBPAC meeting for this product is not warranted. A justification will be required, along with inclusion of the appropriate language, in the final Action letter.
- All communications with the Sponsor, up to this midcycle period, should be uploaded to the EDR within the next two weeks.
- Draft reviews should be sent to the committee chair and RPM as well as the reviewer's Branch Chief.

Milestones:

Application Received:	September 30, 2008
Committee Assignment:	October 13, 2008 (completed October 10, 2008)
First Committee Meeting:	October 21, 2008 (conducted October 20, 2008)
Filing Meeting:	November 15, 2008 (conducted via e-mail November 7, 2008)
Filing Action:	November 29, 2008 (completed November 24, 2008)
Deficiencies Identified:	December 13, 2008 (completed – included in Filing Letter)
Action Due Date (ADD):	July 31, 2009