



## Filing Meeting

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

**Date:** November 7, 2008  
**To:** BLA 125296/0 File  
**From:** Daryll L. Miller, M.A., Committee Chairperson  
**Type:** Filing 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 filing meeting is to determine the acceptability of the application for filing. An email request was sent out to the Review Committee on Friday, November 7, 2008, to determine if the section of the application assigned for their review is acceptable for filing. A determination of fileable does not represent any evaluation of the adequacy of the data submitted.

Each reviewer responded indicating that the application is fileable. Three reviewers identified the following potential review issues which will be sent to Duramed in a separate information request letter either via secure email or fax.

### Issue 1:

How were the clinical assays carried out? Were the assays performed by multiple people and at multiple times? If so, does the BLA contain those multiple measurements? If not what measurements were selected for the efficacy data to prevent bias?

### Issue 2:

The sponsor needs to submit a request for proprietary name review with a rationale of use and the results of any independent study, if one was conducted. If the proprietary name is changed from the name submitted in the BLA, the labeling (FPI, vial and carton labels) should reflect that change.

### Issue 3:

The sponsor states that they plan to (b)(4) the lyophilization capacity from the current-----  
---(b)(4)----- of Lyophilized Intermediate for commercial production of the product after approval. To achieve this scale, the sponsor plans to --(b)(4)-- the Formulated Virus manufacturing process to formulate batch size from the current -----(b)(4)-----  
----- . However, validation data for --(b)(4)-- lyophilization and mixing studies have not been submitted. We would like to remind the sponsor that without the validations for --(b)(4)-- lyophilization and mixing study, we can only approve the current validated scales.

### Issue 4:

The sponsor states that the final report for cleaning validation for ADV 4 and ADV 7 and residual solvents in Barr Laboratories has not been completed. Only an interim report for

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cleaning validation has been submitted in this BLA. The sponsor needs to submit a summary of the final report for cleaning validation for each piece of product-contact equipment and the facility.

Issue 5:

The sponsor needs to clarify if they have completed aseptic process validation at the ---(b)(4)--- facility. If so, the sponsor needs to submit a summary report.

**Meeting Participants:**

<u>Name</u>	<u>BLA Review Role</u>	<u>Fileable Determination</u>
Daryll Miller	Chairperson	YES
Helen Gemignani	Co-Regulatory Project Manager	YES
Darlene Hithe	Co-Regulatory Project Manager	YES
Barry Falgout	CMC	YES
Lewis Schragar	Clinical	YES
Mridul Chowdhury	Statistics (clinical)	YES
Gang Wang	CMC & Manufacturing Site Inspection	YES
Zhihao (Peter) Qiu	CMC & Manufacturing Site Inspection	YES
Loan Nguyen	Promotional Labeling	YES
Wei Hua	Epidemiology	YES
Solomon Yimam	Bioresearch Monitoring	YES
Rajesh Gupta	CMC & DPQ Product Testing	YES
David Schwab	Electronic Integrity	N/A

**Milestones:**

Note: Milestone dates have been adjusted to reflect the change of the application receipt date from October 1, 2008 to September 30, 2008.

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 \(effectively due November 28, 2008\)](#)  
Deficiencies Identified: [December 13, 2008 \(effectively due December 12, 2008\)](#)  
Action Due Date (ADD): [July 31, 2009](#)

**Action Items:**

The action items requested should be communicated to the RPMs and Chair on or before the requested due date.

<b>Action Requested</b>	<b>Responsible Party</b>	<b>Due Date Requested</b>
Identify deficiencies in BLA	All Reviewers	December 4, 2008
Identify scheduled date of inspections	Gang Wang, Peter Qiu, and Solomon Yimam	December 4, 2008

If you have questions during the course of the review, please contact the Chair or the RPMs. If you have electronic issues you may contact David Schwab directly.

**Contact Information:**

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**Sent via e-mail to the Adenovirus Type 4 & 7 BLA review team on November 21, 2008:**

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Helen Gemignani  
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Barry Falgout  
Lewis Schragar  
Mridul Chowdhury  
Gang Wang  
Zhihao (Peter) Qui  
Loan Nguyen  
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