

From: Miller, Daryll L
Sent: Friday, June 27, 2008 11:20 AM
To: Markoff, Lewis; Daemer, Richard J.
Cc: Chowdhury, Mridul; Roberts, Jeff
Subject: Information from Paul Wilson

I also spoke to Paul about the data for study 310. He says it will be uploaded on Monday or Tuesday. They wanted to get us the summary first but they will definitely be uploading it next week. Dick, I may not be here so would you please make sure to route the amendment to Mridul and Jeff?

Finally, I asked Paul about the study in children in India that Laraine mentioned on Wednesday in the monthly update. It is study IC51-221. The study is complete and they are very happy with their results. They used 60 children between the ages of 1 and 3 and got 98% seroconversion and GMT's of >200 so they are planning to move forward with a Phase 3 study including children in the US.

Daryll L. Miller, M.A.
Regulatory Health Project Manager
FDA/CBER/OVRR/DVRPA
HFM-478
1401 Rockville Pike, Suite 370N
Rockville, MD 20852
Telephone: 301-827-3070
Fax: 301-827-3532

From: Miller, Daryll L
Sent: Friday, June 27, 2008 12:54 PM
To: 'Paul WILSON'
Cc: Markoff, Lewis; Daemer, Richard J.
Subject: RE: Lot Release Protocol
Hi Paul,

A lot release protocol should have the following elements included:

- Lot designation, lot size, expiration date
- Lot #s for drug substance lots used in final product formulation
- Results from critical in process tests for control cells and drug substance with specifications included
- Results from final container release tests with specifications included

We suggest that you put together a draft protocol incorporating these items and once we receive it, we can work with you to finalize it.

Regards,
Daryll

From: Paul WILSON [mailto:PWILSON@intercell.com]
Sent: Friday, June 27, 2008 12:30 PM
To: Miller, Daryll L
Subject: Lot Release Protocol

Hi Daryll:

I wanted to get back with you regarding your question about the lot release protocol. The tests along with acceptance criteria that are done on the Drug Substance and the Drug product are mentioned in BLA sections 32S41 and 32P42, respectively. In addition to this, we will submit and upload to the BLA other documents (like SOPs, etc.) involved in the Lot release on Monday or latest by Tuesday.

Also, as previously discussed, we will also submit the clinical datasets on Study 310 on Monday or Tuesday.

Please let me know if you have any further comments or questions.

Have a good weekend!!

Best, Paul

Paul J. Wilson
President & CEO
Intercell USA Inc.
179 Castles Gate Drive
Mooresville, NC 28117
Tel: 704-799-0196
Fax: 704-799-0161
Mobile: 704-763-7704
Email: PWilson@Intercell.com or

(b)(6)