

System Info - 86617 MILLER, DARYLL 13-Feb-2009 17:06:16 MILLERD

## RECORD OF TELEPHONE CONVERSATION

Submission Type: Original Application Submission ID: 125280/0 Office: OVR

Product:  
Japanese Encephalitis Virus Vaccine Inactivated

Applicant:  
Intercell AG

Telecon Date/Time: 12-NOV-2008 12:00 AM Initiated by FDA? Yes  
Telephone Number:

Communication Category(s):  
Other

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Telecon Summary: Discussion of Lot Release Issues  
Lot Release issues

### FDA Participants:

Dick Daemer  
Lew Markoff  
Li Yu  
Bill McCormack  
Joseph Quander III  
Daryll Miller

### Non-FDA Participants:

Thomas LINGELBACH, COO, Intercell AG  
David VENABLES; Site Director, Intercell Biomedical  
Christoph KLADE; Technology Development / Clinical Immunology  
Murray MCKAY, Quality Operations  
Fraser LESLIE; Quality and Regulatory Compliance  
Shailesh DEWASTHALY, Regulatory Affairs, Intercell AG  
Paul WILSON, Intercell USA

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

- Sponsor's specification for (b)(4)
- The results of CBER testing for this parameter
- Problems with the use of the Lot Release Protocol Template