

RECORD OF TELEPHONE CONVERSATION

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

Product:  
Japanese Encephalitis Virus Vaccine Inactivated

Applicant:  
Intercell AG

Telecon Date/Time: 03-FEB-2009 12:00 AM Initiated by FDA? Yes  
Telephone Number:

Communication Category(ies):  
Information Request

Author: DARYLL MILLER

Telecon Summary:  
Information needed regarding PMV, Peds Plan and (b)(4) Method

FDA Participants:  
Daryll Miller  
Richard Daemer

Non-FDA Participants:  
Paul Wilson

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:  
Discussed timelines for PMV plan to be included in approval letter.

- Sponsor committed to providing protocols between 3 and 6 months following approval.
- Sponsor will provide the date they expected to begin the study as well as the date that the clinical study report will be submitted for each study.

The Pediatric study details will be submitted by the following Thursday. They plan to perform an Interim Analysis of the data to determine if enrollment matches prediction of

percentage of subjects with no antibodies to JE. If not, enrollment will be increased.  
Details to follow.

(b)(4) method is currently being used and has been submitted previously  
to the BLA.