

System Info - 86594 MILLER, DARYLL 13-Feb-2009 15:48:06 MILLERD

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: 07-AUG-2008 12:00 AM Initiated by FDA? Yes  
Telephone Number:

Communication Category(ies):  
Advice

Author: DARYLL MILLER

Telecon Summary:  
Telecon regarding Lot Release protocols and sample testing

FDA Participants:  
Lew Markoff  
Daryll Miller  
Richard Daemer  
Bill McCormick  
Joe Quander III

Non-FDA Participants:  
From Intercell Biomedical Limited (Livingston, Scotland)  
David Venables, Operations Site Director  
Fraser Leslie, Head of Quality & Regulatory Compliance  
Murray McKay, Head of Quality Operations  
Petra Eaglesfield, Head of Regulatory Affairs  
Paul Derbyshire, Consultant

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Discussion of (b)(4) protein testing and specification. Discrepancies in specification and results in testing were noted by CBER.

Sponsor will correct protocol from (b)(4) of (b)(4) protein for LRP.

CBER requested 50 filled syringes for each lot to be tested.

Intercell will expand template with respect to cell information for each lot submitted.

Results to be sent to BLA as amendment.

(b)(4) assay is being developed as an identity test. Sponsor agreed to provide additional information. CBER noted that identity test must be performed on final containers.