

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

Communication Category(ies):
Response to Information Provided

Author: DARYLL MILLER

Telecon Summary: Discussion of Sponsor's responses to information request of July 25, 2008

FDA Participants:
Dick Daemer
Destry Sullivan
Daryll Miller

Non-FDA Participants:
Paul Wilson

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:
Discussion of responses to information request:
1. CBER requested additional information.
2. Not adequately explained. No validation was provided.
3. Not cross-referenced in DMF.

4. Problematic. Need discussion with (b)(4) (filing facility for syringes). Requested validation report was not provided.
5. and 6. Information to be provided by Sponsor by August 25, 2008. Destry Sullivan requested that information be provided as soon as possible. Sponsor agreed.