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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: 04-DEC-2008 12:00 AM

Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

1. Advice
2. Other

Author: DARYLL MILLER

Telecon Summary:

Testing issues re: (b)(4)

FDA Participants:

Lew Markoff

Dick Daemer

Daryll Miller

Bill McCormick

Al Del Grosso

Brandon Duong

Non-FDA Participants:

Joanna HOPE, Laboratory Head Biochemistry, Quality Control, Intercell Biomedical

Mario NEBENFUHR, Staff Scientist, Analytical and Formulation Development, Intercell AG

Christoph KLADE, Technology Development / Clinical Immunology, Intercell AG

Fraser LESLIE, Quality and Regulatory Compliance, Intercell Biomedical

Paul WILSON, Intercell USA

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Review of testing procedure for (b)(4) of protein, including (b)(4), reagents, (b)(4) etc. CBER noted that in their retesting the results were worse than initial testing. Possible discrepancy between (b)(4) (b)(4) was noted. Sponsor suggested sending their own lab personnel to CBER for side testing.

CBER noted only validation reports were in the BLA. Sponsor agreed to send the appropriate SOPs as well as additional samples.