

System Info - 88434 MILLER, DARYLL 06-Mar-2009 17:43:47 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: 06-MAR-2009 12:00 AM Initiated by FDA? Yes
Telephone Number:

Communication Category(ies):
Information Request

Author: DARYLL MILLER

Telecon Summary:
Information request regarding Lot (b)(4) of JE vaccine and whether (b)(4) assay
is being used to test for (b)(4) in the Drug Substance

FDA Participants:
Lew Markoff
Daryll Miller
Richard Daemer
Bill McCormick
Al Del Grosso
Destry Sullivan
Li Yu

Intercell Participants:
Paul Wilson
Fraser Leslie
David Venables
Thomas Lingelbach

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

CBER requested a telecon with Intercell :

1. to determine the status of Lot (b)(4) which was not sent by Intercell for testing as expected and also
2. to determine if Intercell is using the (b)(4) assay for determining (b)(4) at the Drug Substance stage.

Intercell explained that they have 3 lots available for testing but that they expect to have approval from the European community earlier than our possible approval. They selected Lot (b)(4) for the European commercial lot because of size and availability. They sent Lots (b)(4) to CBER because Lot (b)(4) is only (b)(4) doses and Lot (b)(4) will not be available as early as Lot (b)(4).

Intercell is also in the process of testing (b)(4) batches of drug substance in parallel with both the old and new assay procedures for (b)(4) and expect to have validation by April 14, 2009. They will forward the report as soon as possible and they have agreed to a 3 month post-approval deadline on switching procedures to the (b)(4) assay.

During the telecon, Intercell asked CBER for an update regarding the compliance issues at the (b)(4) facility. CBER informed Intercell that they will be having a telecon with CDER and (b)(4) on Wednesday, March 11, 2009 and will give Intercell an update on the compliance issues as soon as possible after the telecon.

Intercell agreed to wait to hear from CBER regarding compliance.