

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: 23-MAR-2009 01:45 PM

Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):

1. Advice
2. Information Request

Author: DARYLL MILLER

Telecon Summary:

Discussion about compliance, pediatric studies, and -----(b)(4)----- Assay

FDA Participants:

Daryll Miller

Richard Daemer

Non-FDA Participants:

Paul Wilson

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

1. Requested communication received from CDER regarding -(b)(4)- inspection status.
2. Informed Mr. Wilson that protocol IC51-321 will not be a requirement for US license because Intercell will be using a non-US licensed vaccine as a comparator.
3. Asked for assurance that protocol IC51-323 will use a US licensed Hepatitis A vaccine.
4. Requested that Intercell provide an amendment to the BLA which contains a commitment to provide the validation data for the -----(b)(4)----- Assay

(b)(4) "Rosa, Carmelo R" An (b)(6)
<Carmelo.Rosa@fda.hhs.gov> Kopie
20.03.2009 19:35 Blindkopie
Thema RE: FW: FDA feedback ?
(b)(4)

Dear Otto,

We appreciate your visit to FDA CDER-OC on 03/11/09, to discuss the status of the inspections conducted to the (b)(4) facilities in Germany and present your corrective actions and commitments to the agency. We are classifying all three inspections as (b)(5) which means that your proposed corrective actions and commitments made to the agency are considered acceptable. The status of your (b)(4) facility, related to NDA (b)(4) was also updated. A formal written communication from the agency should be received by you in the up coming weeks.

Kindest Regards,

Carmelo Rosa, M.S., Psy.D
Compliance Officer
CDER Office of Compliance/Division of Manufacturing
and Product Quality/International Compliance Branch
10903 New Hampshire Ave. Building 51, Rm 4240
Silver Spring, MD 20903
(301)796-3667; Fax (301) 847-8741

From: Paul Wilson [PWilson@intercell.com]
Sent: Monday, March 23, 2009 2:47 PM
To: Miller, Daryll L
Cc: Daemer, Richard J.
Subject: RE: BLA Status

Attachments: CDER FAX TO (b)(4).pdf; emfinfo.txt
Further, attached is a copy of the CDER fax to (b)(4). Best, Paul

From: Paul Wilson
Sent: Monday, March 23, 2009 2:44 PM
To: 'Miller, Daryll L'
Cc: 'Richard.Daemer@fda.hhs.gov'
Subject: RE: BLA Status

Hi Dick and Daryll:

Dick & Daryll,

Responding to a couple of the issues we just discussed:

- 1- As I expected, Intercell is planning to use a US-licensed Hepatitis A vaccine for the post-licensure pediatric study 323.
- 2- We will upload tomorrow a BLA Amendment related to the commitment for the (b)(4) assay.

One question: On last Friday, Murray McKay from Intercell responded to Destry's request as shown in the email below. I trust this response was OK as we never heard back from Destry.

Best, Paul

From: Murray MCKAY
Sent: Friday, March 20, 2009 7:06 AM
To: Sullivan, Destry
Cc: Paul Wilson; David VENABLES; Miller, Daryll L; Daemer, Richard J.
Subject: RE: Intercell 483 observation 1b (ii)

Hi Destry

Yes, this has been submitted through the gateway under an amendment 0010 dated September 25, 2008.

The file is located under this section,

M1-11-1-Quality-information-amendment

file title: 483-response-0010
page: 94 to 237.

Unfortunately the file is too large to send by email.

Regards

Murray

From: Miller, Daryll L [mailto:Daryll.Miller@fda.hhs.gov]
Sent: Monday, March 23, 2009 1:08 PM
To: Paul Wilson
Cc: Daemer, Richard J.
Subject: RE: BLA Status

Hi Paul,

Do you have a few minutes to talk with Dick and me at about 1:30? We will call you.

Daryll

From: Paul Wilson [mailto:PWilson@intercell.com]
Sent: Monday, March 23, 2009 8:02 AM
To: Daemer, Richard J.; Miller, Daryll L
Cc: Markoff, Lewis
Subject: BLA Status

Hi Dick and Daryll,

Intercell has received confirmation from (b)(4) that they received the written, (b)(5) classification from CDER last Friday. Have you & others at CBER been notified of this positive outcome? If so, we are hoping that the BLA for IXIARO can now move forward to final approval before the action due date (April 3rd).

I am not aware of any remaining open issues on the BLA. I may touch base with you this morning to make sure that I am not missing something.

I would sincerely appreciate your help and support in finalizing everything before the action due date. Many thanks in advance!!!

All the best, Paul

for determining -----(b)(4)----- of the Drug Substance within 3 months following product licensure.

Please see attached e-mail and fax for responses to comments 1, 3 and 4 above.
Comment 2 was for information only.