

Record of Email Communication, April 20 - May 3, 2010 - MenHibrix

From: Bridgewater, Jennifer
Sent: Monday, May 03, 2010 9:18 AM
To: Norwood, Laurie; Renshaw, Carolyn; Roecklein, Tina; George, Joseph; Byrd, Sean (CBER); Eltermann, John
Cc: Trout, Deborah; Vann, Willie
Subject: RE: Menhiberix BLA 125363

Let's not go that route then. If DMPQ doesn't usually need this site info for this level of test, perhaps we should pass on it and try to work on getting some type of validation information into the file. Will that work?

Jennifer

From: Norwood, Laurie
Sent: Monday, May 03, 2010 8:53 AM
To: Renshaw, Carolyn; Roecklein, Tina; Bridgewater, Jennifer; George, Joseph; Byrd, Sean (CBER); Eltermann, John
Cc: Trout, Deborah; Vann, Willie
Subject: RE: Menhiberix BLA 125363

This could take months if they do not have an FEI number.

Laurie P. Norwood
Deputy Director
Division of Manufacturing and Product Quality
OCBQ/CBER/FDA
301-827-3031

From: Renshaw, Carolyn
Sent: Monday, May 03, 2010 8:40 AM
To: Roecklein, Tina; Norwood, Laurie; Bridgewater, Jennifer; George, Joseph; Byrd, Sean (CBER); Eltermann, John
Cc: Trout, Deborah; Vann, Willie
Subject: RE: Menhiberix BLA 125363

OK – Joe can follow-up with the firm to obtain an FEI number and request a compliance check.

Carolyn Renshaw
Branch Chief, MRB 1
FDA/CBER/OCBQ/DMPQ
5516 Nicholson Lane

Kensington, MD 20895

From: Roecklein, Tina
Sent: Sunday, May 02, 2010 10:19 PM
To: Norwood, Laurie; Renshaw, Carolyn; Bridgewater, Jennifer; George, Joseph; Byrd, Sean (CBER); Eltermann, John
Cc: Trout, Deborah; Vann, Willie
Subject: RE: Menhiberix BLA 125363

DBPAP feels that this is an important test and that they are choosing to test at the (b)(4) stage and not (b)(4). However, we will go with whatever DMPQ feels is appropriate. Thanks.

Tina Roecklein, M.S.
Consumer Safety Officer
DBPAP/OVRR/CBER/FDA
Tel: (301) 827-3026
Fax: (301) 402-2776

From: Norwood, Laurie
Sent: Friday, April 30, 2010 10:55 AM
To: Renshaw, Carolyn; Bridgewater, Jennifer; George, Joseph; Byrd, Sean (CBER); Roecklein, Tina; Eltermann, John
Cc: Trout, Deborah
Subject: RE: Menhiberix BLA 125363

Historically compliance checks for test labs are conducted for final drug product and critical tests for (b)(4), such as viral clearance, inactivation, etc.

Laurie P. Norwood
Deputy Director
Division of Manufacturing and Product Quality
OCBQ/CBER/FDA
301-827-3031

From: Renshaw, Carolyn
Sent: Friday, April 30, 2010 10:41 AM
To: Bridgewater, Jennifer; George, Joseph; Byrd, Sean (CBER); Roecklein, Tina; Eltermann, John; Norwood, Laurie
Cc: Trout, Deborah
Subject: RE: Menhiberix BLA 125363

My understanding is that analytical testing for less complex and less critical tests of intermediates and drug substance do not require compliance checks for their compliance status. Jay or Laurie, please correct me if I'm wrong. The policy on this is not clear to me.

Carolyn Renshaw

Branch Chief, MRB 1
FDA/CBER/OCBQ/DMPQ
5516 Nicholson Lane
Kensington, MD 20895

From: Bridgewater, Jennifer
Sent: Friday, April 30, 2010 10:21 AM
To: George, Joseph; Byrd, Sean (CBER); Roecklein, Tina
Cc: Renshaw, Carolyn
Subject: RE: Menhiberix BLA 125363

Thanks Joe. I'm going to defer the question regarding importance of the test to Tina. She has looked at ---
--(b)(4)----- . Just to clarify, is OCBQs position that contract testing on intermediates is not
something we check on compliance status for in general? Do we only look at sites for drug product? What
about drug substance? ----(b)(4)----- is of course a residual that we are concerned about for vaccines.
However, the level should be barely detectable to essentially non-existent in final product. I'm not sure if
we have validation data for the test at this site, whether there was some kind of tech transfer or the
like. Maybe this is something we need to ask for on our end.

Thanks,
Jennifer

From: George, Joseph
Sent: Friday, April 30, 2010 10:11 AM
To: Bridgewater, Jennifer; Byrd, Sean (CBER); Roecklein, Tina
Cc: Renshaw, Carolyn
Subject: RE: Menhiberix BLA 125363

Since this testing is performed on the --- ----(b)(4)-----, I'm not sure inspectional history is
needed. However, to be sure, can you please tell me how critical this test is?

- Joe

Joseph George
Consumer Safety Officer
FDA/CBER/OCBQ/Division of Manufacturing & Product Quality
v: 301-827-6926
f: 301-594-6530

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From: Bridgewater, Jennifer
Sent: Tuesday, April 20, 2010 11:04 AM
To: Byrd, Sean (CBER); George, Joseph; Roecklein, Tina
Subject: Menhiberix BLA 125363

Hi all -

In QC'ing some of the product reviews, I came across the following in GSKs amendment 3 for the Menhiberix BLA. In the original submission, GSK lists only GSK related sites as performing product testing and manufacturing. In amendment 3, they now list a contract lab as performing -----(b)(4)-----
- testing. I have not researched this issue any further than noticing it. I am including the page from the original BLA and from Amendment 3 for your reference. Both pages can be found in the Quality Section 3, specifically Drug Substance Hib-TT, Manufacture, Section 3.2.S.2.1 (go to this section in both original BLA and amendment 3).

Is this something to be concerned about? Don't they need inspection clearance for contract testing sites? Have we ever looked at this site? Sean and Joe can you follow-up on this from the inspectional side and see if there is an issue here?

Thanks,
Jennifer

<< File: manufacturer 3.2 Hib-TT BLAamend3.pdf >> << File: manufacturer 3.2 Hibtt original BLA.pdf >>