

Lee, Mark H (FDA)

From: Kristine Riley [KRiley@Organo.com]
Sent: Wednesday, February 29, 2012 4:09 PM
To: Lee, Mark H (FDA)
Subject: Re: Update regarding Master File for rh-insulin

Hi Mark:

The rh-insulin will be [REDACTED]

Best regards,
Kristine

From: Lee, Mark H (FDA) [mailto:Mark.Lee@fda.hhs.gov]
Sent: Wednesday, February 29, 2012 12:18 PM
To: Kristine Riley
Subject: RE: Update regarding Master File for rh-insulin

Kristine,

Regarding this issue, can you clarify the date at which [REDACTED] insulin?

Thanks,
Mark

From: Kristine Riley [mailto:KRiley@Organo.com]
Sent: Wednesday, February 29, 2012 10:31 AM
To: Lee, Mark H (FDA)
Subject: RE: Update regarding Master File for rh-insulin

Thanks Mark

From: Lee, Mark H (FDA) [mailto:Mark.Lee@fda.hhs.gov]
Sent: Wednesday, February 29, 2012 10:29 AM
To: Kristine Riley
Subject: RE: Update regarding Master File for rh-insulin

Kristine,

Thanks for the information. We'll discuss internally and I'll advise further if additional information is needed for the BLA.

Best,
Mark

From: Kristine Riley [mailto:KRiley@Organo.com]
Sent: Tuesday, February 28, 2012 4:05 PM

3/12/2012

To: Lee, Mark H (FDA)
Subject: RE: Update regarding Master File for rh-insulin

Hi Mark:

We purchase our rh-insulin from a distributor [REDACTED]
[REDACTED] sells to. We have a Quality/Service agreement with [REDACTED] is the DMF holder for the rh-insulin. To obtain a cross-reference to the DMF we need to have a Service agreement with [REDACTED] In addition, last week, [REDACTED]

We are working diligently to finalize the Service agreement with [REDACTED]

Best regards,
Kristine

From: Lee, Mark H (FDA) [mailto:Mark.Lee@fda.hhs.gov]
Sent: Tuesday, February 28, 2012 2:45 PM
To: Kristine Riley
Subject: Update regarding Master File for rh-insulin

Kristine,

I'm trying to close out any pending issues while finalizing our CMC review document. In amendment 0027, it was indicated that OI had requested a formal cross-reference authorization to the master file for rh-insulin from [REDACTED] Have you received this yet and have provided it in the BLA?

Thanks,

Mark

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3/12/2012

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