

[Redacted]

From: [Redacted] <[Redacted]@abbott.com>
Sent: 31 January 2023 04:52
To: Bellahn, Inga
Cc: [Redacted]
Subject: RE: Librelink connectivity - FSN
Attachments: ADC Response MHRA Follow Up Letter 30Jan23.pdf; [Redacted]
Follow Up Flag: Follow up
Flag Status: Flagged

Dear Inga,

Please find attached ADC’s additional set of responses to the inquiries raised by MHRA as well as the draft copy of the Field Safety Notice for MHRA review and feedback, as requested.

Regards,



[Redacted]

Abbott Diabetes Care
1360 South Loop Road
Alameda, CA 94502

M: +[Redacted]
[Redacted]@abbott.com
Building 2901-01

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From: [Redacted]
Sent: Friday, January 27, 2023 5:56 PM
To: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>; [Redacted] <[Redacted]@abbott.com>
Subject: RE: Librelink connectivity - FSN

Dear Inga,

Please find attached ADC’s initial set of responses to the inquiries raised by MHRA, as well as a draft copy of the field safety notice we discussed during our meeting yesterday.

Thank you for making yourself available for a meeting on Monday. We would like to confirm 3pm and look forward to speaking with you then.

Regards,



[Redacted]

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From: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>
Sent: Friday, January 27, 2023 1:15 PM
To: [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>
Cc: [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>
Subject: RE: Librelink connectivity - FSN

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Dear [REDACTED],
Thank you for the update, that is helpful to know.

I would be available from 3pm on Monday, would that be suitable for you?

Kind regards
Inga

From: [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>
Sent: 27 January 2023 17:03
To: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>
Cc: [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>
Subject: RE: Librelink connectivity - FSN

Dear Inga,

Thank you also for making yourself available at short notice to discuss the items with us this week.

The draft FSN and responses (per the MHRA follow-up letter) to other items due today are in review with our technical subject matter experts in our head-quarters in the US. This is to ensure that all information provided is precise and aligned to the feedback the MHRA have kindly provided. Our team will be sending this information across to you at the latest COB US time.

If at all acceptable to you, would you have any availability Monday 30th January for a call where we could provide any clarifications that you have on the material that will be sent to you today and also brief you on additional items that have been identified?

Thanks again.

[REDACTED]



[REDACTED]
EMEAP

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From: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>
Sent: 27 January 2023 16:32
To: [REDACTED] [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>
Subject: Librelink connectivity - FSN

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Dear [REDACTED],

Many thanks again for meeting yesterday and for your flexibility around timing.

Would you be able to confirm if Abbott will submit a draft FSN by COB today as indicated?

Kind regards
Inga

Inga Bellahn, PhD
Head of Metabolic Disorders and Renal Systems
Benefit/Risk Evaluation II, Safety and Surveillance Group
Medicines and Healthcare Products Regulatory Agency
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[Read our guidance on coronavirus \(COVID-19\)](#)

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