

[Redacted]

From: [Redacted]@abbott.com>
Sent: 01 February 2023 21:13
To: Bellahn, Inga; [Redacted]
Cc: [Redacted] WWPQA; ADC Complaints QA; [Redacted]
Subject: RE: Librelink connectivity - FSN/[Redacted]
[Redacted]

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Inga,

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

May I also please request a call with yourself to update you on the Android issue, which we have been discussing a draft FSN on? I am happy to work around your schedule if you can send me a convenient timeslot per your calendar.

Thanks again.

[Redacted]



[Redacted]
EMEAP

Abbott Diabetes Care Ltd
Range Road
Witney
Oxfordshire
OX29 0YL

O: [Redacted]
[Redacted]@[abbott.com](mailto:[Redacted]@abbott.com)

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From: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>

Sent: 01 February 2023 19:01

To: [REDACTED]@abbott.com>; [REDACTED]@abbott.com>

Cc: [REDACTED]@mhra.gov.uk>; [REDACTED]@mhra.gov.uk>

Subject: RE: Librelink connectivity - FSN/[REDACTED]

EXTERNAL EMAIL: Only click links or open attachments if you recognize the sender and know the content is safe.

Thank you, [REDACTED]

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
10 South Colonnade, Canary Wharf, London, E14 4PU
✉ inga.bellahn@mhra.gov.uk

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From: [REDACTED]@abbott.com>

Sent: 01 February 2023 18:55

To: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>; [REDACTED]@abbott.com>

Cc: [REDACTED]@mhra.gov.uk>; [REDACTED]@mhra.gov.uk>

Subject: RE: Librelink connectivity - FSN/[REDACTED]

Dear Inga,

[REDACTED]

Thanks again.
[REDACTED]



[REDACTED]
EMEAP

Abbott Diabetes Care Ltd
Range Road
Witney
Oxfordshire
OX29 0YL

O: [REDACTED]
[REDACTED]@abbott.com

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From: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>

Sent: 01 February 2023 18:42

To: [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>; [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>

Cc: [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>; [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>

Subject: RE: Librelink connectivity - FSN/[REDACTED]

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Dear [REDACTED],

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
10 South Colonnade, Canary Wharf, London, E14 4PU
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From: [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>

Sent: 01 February 2023 14:00

To: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>; [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>

Cc: [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>; [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>

Subject: RE: Librelink connectivity - FSN/[REDACTED]

Thanks Inga.



[REDACTED]
EMEAP

Abbott Diabetes Care Ltd
Range Road
Witney
Oxfordshire
OX29 0YL

O: [REDACTED]
[REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>

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From: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>

Sent: 01 February 2023 13:52

To: [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>; [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>

Cc: [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>; [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>

Subject: RE: Librelink connectivity - FSN/[REDACTED]

EXTERNAL EMAIL: Only click links or open attachments if you recognize the sender and know the content is safe.

Thank you, [REDACTED]
[REDACTED]

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
10 South Colonnade, Canary Wharf, London, E14 4PU
✉ inga.bellahn@mhra.gov.uk

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From: [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>

Sent: 01 February 2023 13:50

To: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>; [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>

Cc: [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>; [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>

Subject: RE: Librelink connectivity - FSN/[REDACTED]

Hi Inga,

[REDACTED]

[REDACTED]

Thanks,
[REDACTED]



[REDACTED]
EMEAP

Abbott Diabetes Care Ltd
Range Road
Witney
Oxfordshire
OX29 0YL

O: [REDACTED]
[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)

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From: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>
Sent: 01 February 2023 13:43
To: [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>; [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>
Cc: [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>; [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>
Subject: RE: Librelink connectivity - FSN/[REDACTED]

EXTERNAL EMAIL: Only click links or open attachments if you recognize the sender and know the content is safe.

Dear [REDACTED],

[REDACTED]

[REDACTED]

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
10 South Colonnade, Canary Wharf, London, E14 4PU
✉ inga.bellahn@mhra.gov.uk

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From: [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>
Sent: 01 February 2023 13:38
To: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>; [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>
Cc: [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>; [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>
Subject: RE: Librelink connectivity - FSN/[REDACTED]

Dear Inga,

[REDACTED]

[REDACTED]

Thanks,

[REDACTED]



[REDACTED]
EMEAP

Abbott Diabetes Care Ltd
Range Road
Witney
Oxfordshire

O: [REDACTED]
[REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>

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From: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>

Sent: 01 February 2023 13:10

To: [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>; [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>

Cc: [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>; [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>

Subject: RE: Librelink connectivity - FSN/[REDACTED]

Importance: High

EXTERNAL EMAIL: Only click links or open attachments if you recognize the sender and know the content is safe.

Dear [REDACTED], dear [REDACTED]

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
10 South Colonnade, Canary Wharf, London, E14 4PU

✉ inga.bellahn@mhra.gov.uk

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From: [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>

Sent: 01 February 2023 04:28

To: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>; [REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>

Cc: [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>; [REDACTED] <[\[REDACTED\]@mhra.gov.uk](mailto:[REDACTED]@mhra.gov.uk)>

Subject: RE: Librelink connectivity - FSN/[REDACTED]

Dear Inga,

[Redacted]



[Redacted]

Abbott Diabetes Care
1360 South Loop Road
Alameda, CA 94502

[Redacted]

[@abbott.com](mailto: [Redacted]@abbott.com)

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From: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>
Sent: Tuesday, January 31, 2023 6:43 AM
To: [Redacted] <[\[Redacted\]@abbott.com](mailto: [Redacted]@abbott.com)>; [Redacted] <[\[Redacted\]@abbott.com](mailto: [Redacted]@abbott.com)>
Cc: [Redacted] <[\[Redacted\]@mhra.gov.uk](mailto: [Redacted]@mhra.gov.uk)>; [Redacted] <[\[Redacted\]@mhra.gov.uk](mailto: [Redacted]@mhra.gov.uk)>
Subject: Librelink connectivity - FSN/[Redacted]

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Dear [Redacted] dear [Redacted]
Could you please ensure that [Redacted] and [Redacted] will be copied in when you submit the two updated FSNs to us.

Many thanks.

Kind regards
Inga

From: Bellahn, Inga
Sent: 31 January 2023 12:56
To: [Redacted] <[\[Redacted\]@abbott.com](mailto: [Redacted]@abbott.com)>
Cc: [Redacted] <[\[Redacted\]@abbott.com](mailto: [Redacted]@abbott.com)>
Subject: FW: Librelink connectivity - FSN

Dear [Redacted] dear [Redacted]

Please see

MHRA comments below:

- There are 2 FSNs going out at the same time, it needs to be really clear at first glance what the message is so the user does not see one and think they have already seen it.

[Redacted content]

Would you be able to submit an updated draft by COB today?

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
10 South Colonnade, Canary Wharf, London, E14 4PU
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From: [Redacted] <[\[Redacted\]@abbott.com](mailto:[Redacted]@abbott.com)>
Sent: 31 January 2023 04:52

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

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,



Abbott Diabetes Care
1360 South Loop Road
Alameda, CA 94502

[REDACTED] <[\[REDACTED\]@abbott.com](mailto:[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](mailto:[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,



Abbott Diabetes Care
1360 South Loop Road
Alameda, CA 94502

[REDACTED] <[\[REDACTED\]@abbott.com](mailto:[REDACTED]@abbott.com)>
Building 2901-01

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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>
Sent: 27 January 2023 17:03
To: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>
Cc: [REDACTED] <[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

Abbott Diabetes Care Ltd
Range Road
Witney
Oxfordshire
OX29 0YL

O: [REDACTED]
[REDACTED]@abbott.com

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From: Bellahn, Inga <Inga.Bellahn@mhra.gov.uk>
Sent: 27 January 2023 16:32
To: [REDACTED] <[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
10 South Colonnade, Canary Wharf, London, E14 4PU
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