From: Sent: To: Cc: Subject:	01 February 2023 Bellahn, Inga; RE: Librelink conn	WWPQA; ADO	C Complaints QA;
Follow Up Flag: Flag Status:	Follow up Flagged		
Dear Inga,			
			sue, which we have been discussing a convenient timeslot per your calendar.
Thanks again.			
🔁 Abbott	EMEAP	Abbott Diabetes Care Ltd Range Road Witney Oxfordshire OX29 oYL	O: . abbott.com

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,

⊠ inga.bellahn@mhra.gov.uk

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Read our guidance on coronavirus (COVID-19)

From: Sent: 01 February 2023 18:55	@abbott.com>	
To: Bellahn, Inga < <u>Inga.Bellahn@mh</u> Cc: Subject: RE: Librelink connectivity -	<u>@mhra.gov.uk</u> >;	@abbott.com> @mhra.gov.uk>
Dear Inga,		

Thanks again.



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From: Bellahn, Inga < <u>Inga.Bel</u> Sent: 01 February 2023 18:42 To: Cc: Subject: RE: Librelink connect	<u>@abbott.com</u> >; <u>@mhra.gov.uk</u> >;	@abbott.com> @mhra.gov.uk>	
EXTERNAL EMAIL: Only click lin	ks or open attachments if you recognize	ze the sender and know the content is safe.	
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: Sent: 01 February 202 To: Bellahn, Inga < <u>Ing</u> Cc: Subject: RE: Librelink	a.Bellahn@mhra.gov.uk @mhra.g		@abbott.com> @mhra.gov.uk>
Thanks Inga.			
🔁 Abbott	EMEAP	Abbott Diabetes Care Ltd Range Road Witney Oxfordshire OX29 oYL	O: . <u>abbott.com</u>

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From: Bellahn, Inga < <u>Inga.Bellahn@mhra.gov.uk</u> >	
Sent: 01 February 2023 13:52	
To: @abbott.com>;	@abbott.com>
Cc: @mhra.gov.uk>;	@mhra.gov.uk>
Subject: RE: Librelink connectivity - FSN/	
EXTERNAL EMAIL: Only click links or open attachments if you recognize the sender	and know the content is safe.
Thank you,	
Kind regards	
Inga	
linga	
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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healthcare-products-regulatory-agency#what-we-do]

Read our guidance on coronavirus (COVID-19)

From: Sent: 01 February 202 To: Bellahn, Inga < <u>Ing</u> Cc: Subject: RE: Librelink	a.Bellahn@mhra.gov.uk>; @mhra.gov.uk	>;	@abbott.com> @mhra.gov.uk>
Hi Inga,			
Thanks,			
C Abbott	EMEAP	Abbott Diabetes Care Ltd Range Road Witney Oxfordshire OX29 oYL	O: . @abbott.com

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From: Bellahn, Inga < <u>Inga.Bellahn@mhra.gov.uk</u> > Sent: 01 February 2023 13:43	
To: <u>@abbott.com</u> >; <u>@abbott.com</u> > Cc: <u>@mhra.gov.uk</u> >; <u>@mhra.gov.uk</u> > Subject: RE: Librelink connectivity - FSN/	
EXTERNAL EMAIL: Only click links or open attachments if you recognize the sender and know the content is safe.	
Dear ,	
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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Read our guidance on coronavirus (COVID-19)

Dear Inga,
Thanks,
Abbott Abbott Diabetes Care Ltd O: . EMEAP Abbott Witney O: . @abbott.com Oxfordshire Oxfordshire O: . Image: Content of the second of the seco

OX29 oYL

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From: Bellahn, Inga <<u>Inga.Bellahn@mhra.gov.uk</u>> Sent: 01 February 2023 13:10

To: Cc: Subject: RE: Librelink cor Importance: High	<u>@abbott.com</u> >; <u>@mhra.gov.uk</u> >;	@abbott.com> @mhra.gov.uk>
EXTERNAL EMAIL: Only clic Dear , dear	ck links or open attachments if you recognize the s	sender and know the content is safe.

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:	@abbott.com>	
Sent: 01 February 2023 04:2	8	
To: Bellahn, Inga < <u>Inga.Bella</u>	hn@mhra.gov.uk>;	@abbott.com>
Cc:	@mhra.gov.uk>;	@mhra.gov.uk>
Subject: RE: Librelink connec	ctivity - FSN/	

Dear Inga,

Abbott	Abbott Diabetes Care 1360 South Loop Road	@abbott.com

From: Bellahn, Inga < <u>Inga.Bellahn@mhra.gov.uk</u> > Sent: Tuesday, January 31, 2023 6:43 AM
To: @abbott.com>; @abbott.com> Cc: @mhra.gov.uk>; @mhra.gov.uk> Subject: Librelink connectivity - FSN/ @mhra.gov.uk>
EXTERNAL EMAIL: Only click links or open attachments if you recognize the sender and know the content is safe.
Dear dear dear control of the 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: @abbott.com> Cc: @abbott.com> Subject: FW: Librelink connectivity - FSN Dear dear

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.



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 Minga.bellahn@mhra.gov.uk

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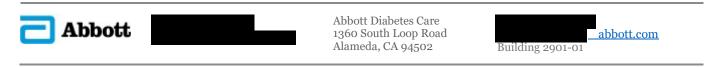
Read our guidance on coronavirus (COVID-19)

To: Bellahn, Inga <<u>Inga.Bellahn@mhra.gov.uk</u>> @abbott.com> Cc: 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,



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From:

Sent: Friday, January 27, 2023 5:56 PM To: Bellahn, Inga <<u>Inga.Bellahn@mhra.gov.uk</u>>; Subject: RE: Librelink connectivity - FSN

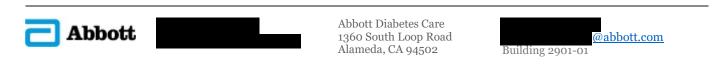
@abbott.com>

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,



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From: Bellahn, Inga <<u>Inga.Bellahn@mhra.gov.uk</u>> Sent: Friday, January 27, 2023 1:15 PM @abbott.com> To: @abbott.com> Cc:

Subject: RE: Librelink connectivity - FSN

Dear

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:
 @abbott.com>

 Sent: 27 January 2023 17:03
 To: Bellahn, Inga <<u>Inga.Bellahn@mhra.gov.uk></u>

 Cc:
 @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.



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From: Bellahn, Inga <<u>Inga.Bellahn@mhra.gov.uk</u>> Sent: 27 January 2023 16:32 To: @abbott.com Subject: Librelink connectivity - FSN

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

Dear

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 inga.bellahn@mhra.gov.uk

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href="<u>https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F_https%3A</u>%2Feur01.safelinks.protection.outlook.com%2F%3Furl%3Dhttps*3A*2F*2Furldefense.com*2Fv3*2F_https*3A*2F eur01.safelinks.protection.outlook.com*2F*3Furl*3Dhttps*3A*2F*2Furldefense.com*2Fv3*2F_https*3A*2Feur01. safelinks.protection.outlook.com*2F*3Furl*3Dhttps*3A*2F*2Furldefense.com*2Fv3*2F_https*3A*2Feur01. *2Fhelp*2Fterms-

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