Message

From: Odusote, Gloria [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ODUSOTE, GLORIA]
Sent: 5/11/2017 2:06:23 PM
To: Szablicka, Monika [monika.szablicka@envigo.com]
Subject: RE: Concerning Your Case

Hi Monika,
Do you want to call? I am not sure what kind of information the company might want to resubmit and I might be able to give better advice if we deal with the specifics.

Best regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Wednesday, May 10, 2017 11:56 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

Our client is preparing the final response however they asked me to confirm with you the following:
If they decide to select Option 3 from the action letter and withdraw the PMN how soon they can re-submit? They are considering changing some information provided in the original PMN. This is very hard decision for them.

Please can you advise?

Thank you.

Kind regards
Monika

Monika Szablicka
Regulatory Specialist
T +44 (0) 1480 892 439
F +44 (0) 1480 892 362
envigo.com

ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Monday, May 08, 2017 7:35 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monika,
If you provide information that there is no inhalation and environmental exposures, the testing would no longer be upfront.
You would still need to respond to the action letter, checking the option that you are providing more information and giving us the time to review the information and write the consent order.

Best,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Monday, May 8, 2017 10:14 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

Thank you very much for your time earlier on. There was one question which I would appreciate you clarification on. If we provide an information that there is no inhalation possibility - would we still need to conduct the studies (OECD 422 and OECD 486)? Would we still have to respond to the action letter?

Thank you
Kind regards
Monika
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F +44 (0) 1480 892 362
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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Monday, May 08, 2017 1:31 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monika,
I'm free today. Feel free to call anytime.

Best regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Monday, May 8, 2017 8:23 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Elliott, Melissa <melissa.elliott@envigo.com>
Subject: RE: Concerning Your Case

Dear Gloria,

Please can you let me know if you are available for the call today?

Thank you.
Kind regards
Monika
Monika Szablicka
Regulatory Specialist
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ENVIGO

From: Szablicka, Monika
Sent: Friday, May 05, 2017 9:49 AM
To: 'Odusote, Gloria'
Cc: Elliott, Melissa
Subject: RE: Concerning Your Case

Dear Gloria,

Please can you let me know when it will be convenient for you so I can call you?

I will be in a meeting until 11am UK time and then between 12.30-14.00pm UK time.

Thank you.
Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Thursday, May 04, 2017 7:29 PM
To: Szablicka, Monika
Cc: Elliott, Melissa
Subject: RE: Concerning Your Case

Hi Monica,
In answering this, I would have to explain the test. Since that is CBI, it would probably be best to explain this over the phone.

Best regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Thursday, May 4, 2017 11:43 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Elliott, Melissa <melissa.elliott@envigo.com>
Subject: RE: Concerning Your Case

Dear Gloria,

Thank you for your kind assistance. Our client is considering the regulatory options and they have some queries. Please can you help us understanding the engineering report, i.e. is there a specific part which we should pay attention to?

In the EPA action letter it is stated that there is a concern for acute toxicity however we have submitted the test report on acute toxicity (please refer to Attachment no. 12 in the original PMN). Additionally, and also as stated in the engineering report the compound does not raise concerns regarding mutagenicity or genetic toxicity in vivo and is unlikely to be carcinogenic. We would really appreciate if you could give us more details as to why the OEDC 422 and OECD 486 are required?

Our client is also considering an analog substance which could possess any data on the health effects information but it is difficult to identify the appropriate analog.

Another question which our client has is whether we can change the application without selecting these 3 options?

Please can you give us your comments regarding the above?

Thank you.

Kind regards
Monika

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: 27 April 2017 18:09
To: Szablicka, Monika
Cc: Elliott, Melissa
Subject: RE: Concerning Your Case

Hi Monika and Melissa,
Yes, you still have the current suspension and since we have been talking, the suspension applies to the action letter as well. Please let me know if there is any way that I can help speed up the process. With the current changes in the EPA, wrapping up the review time for these chemicals has become a priority.

Best regards,
Gloria Odusote

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Wednesday, April 26, 2017 7:33 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>; Elliott, Melissa <melissa.elliott@envigo.com>
Subject: RE: Concerning Your Case
Importance: High

Dear Gloria,

I am aware about the two separate 15 day suspensions to allow us for any review and actions from the engineering report. However I think the 30 days response to the EPA action letter (dated Mar27, 2017) ends today please can you therefore confirm that the extension also applies to this? Unfortunately our client is still considering their final decision.

I appreciate your response at your earliest convenience.
Thank you.

Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Wednesday, April 12, 2017 1:56 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monica,
Do you have the fax number yet? Also your day 90 is coming up. Would you like to request a suspension while you read through the report ad come up with the new information?

Bets regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Wednesday, April 5, 2017 10:15 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

I am sorry for this. I am checking with the technical contact if the fax number is available at her side.

Thank you.

Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Tuesday, April 04, 2017 9:14 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monica,
I hope this email finds you well. I have the engineering report for your case. Do you have a domestic fax number?

Best regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Tuesday, March 28, 2017 10:46 AM

To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

Thank you very much for contacting me with respect to our submission.

I will summarize your concerns with regards to the substance and will inform our client respectively while waiting for the official EPA letter.

If I understood correctly, may I request the engineering controls report to be sent to us via fax?
The number for the fax is: (0044)01480 892362.

Thank you.
Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Tuesday, March 28, 2017 2:09 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monica,
Can you please call me again. Another submitter called me right before you called.

Best regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Tuesday, March 28, 2017 4:50 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

Thank you for your reply. Yes I will call you at 9am EST (2pm UK time).

Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Monday, March 27, 2017 9:01 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monica,
I know it is very late your time. Would you be free to talk tomorrow at 9am EST to talk about your case. Unfortunately, I can't list the PMN number in an email to you as that is CBI.

Best regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Monday, March 27, 2017 11:58 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Ms Odusote,

Thank you for contacting me. I have tried to calling you just now but I understand that you were not available. Please can you let me know which case number you were referring to in your email?

Thank you
Kind regards
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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Monday, March 27, 2017 3:31 PM
To: Szablicka, Monika
Subject: EPA: Concerning Your Case

Hi Ms. Szablicka,
My name is Gloria Odusote and I am the Program Manager for your case. I would like to give you an update on your case.

Please call me at the number below at your earliest convenience.

Best regards,
Gloria Odusote

Gloria Odusote
Chemical Control Division

EPA East
1200 Pennsylvania Ave. NW
Room 4133G, Mail Code 7405M
Washington, DC 20460
202 564-1845
Fax 202 564 9490

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