

FW: Product Lists, Colombia & USTR

From: "Masten, Mia" (b) (6) <[REDACTED]@pfizer.com>
To: "O'Connor, Leslie C. EOP/USTR" <leslie_oconnor@ustr.eop.gov>
Date: Wed, 12 Apr 2017 14:16:59 -0400
Attachments: Pfizer Response to USTR Re Product Denials 3.docx (18.25 kB)

Dear Leslie:

Following up on your request for additional information on the rationale for product denials and delays in Colombia, (b) (4) [REDACTED]
[REDACTED]
[REDACTED]

Thank you,

Mia

Mia T. Masten

Director, Advocacy and Public Affairs

Pfizer, Inc.

cell: (b) (6) [REDACTED]

e-mail: [\[REDACTED\]@pfizer.com](mailto:[REDACTED]@pfizer.com)

[Positivity](#) | [Relator](#) | [Adaptability](#) | [Activator](#) | [Arranger](#)

From: Meacham, Carl (b) (6) <[REDACTED]@phrma.org>

Sent: Thursday, March 23, 2017 3:36 PM

Cc: Kimball, Jonathan

Subject: Product Lists, Colombia & USTR

Hi all,

I hope this note finds you well. Today we met with Assistant U.S. Trade Representative and the US representative to the OECD Trade Committee Dawn Shackleford to discuss our concerns regarding Colombian accession to the OECD. In the meeting, USTR asked if Member companies could provide pertinent information regarding the rationale for product denials and delays in Colombia. USTR made specific reference to the products on the list submitted to BIAC for the background advocacy backgrounder they submitted to the OECD Trade Commission (attached). USTR explained that this would help their arguments with Colombia. To avoid any anti-trust concerns, we encourage you to be in touch directly with Leslie O'Connor (Leslie_OCONNOR@ustr.eop.gov) to provide pertinent information you can share regarding the rationale for any product on the attached list regarding product denials and delays in Colombia.

Thanks, Carl

Carl Meacham

Associate Vice President (LATAM) - International

Pharmaceutical Research and Manufacturers of America

950 F Street, NW Suite 300

Washington, DC 20004

April 12, 2017

Dear Ms. O'Connor:

This letter is in response to your request for additional information on the rationale Colombia used in denying company products listed in the BIAC advocacy backgrounder that was submitted to the OECD Trade Commission. (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Colombia's market access policies and regulatory systems are a significant departure from other regulatory bodies in OECD member countries which leads to unpredictability and uncertainty for the biopharmaceutical industry.

Sincerely,

Mia T. Masten

Colombia

From: "Robinson, Catherine" (b) (6) @pfizer.com>
To: "O'Connor, Leslie C. EOP/USTR" <leslie_oconnor@ustr.eop.gov>
Date: Thu, 13 Jul 2017 12:30:44 -0400

Hi Leslie

Hope all is well. Do you have time this afternoon to chat re: the meeting with the trade minister yesterday? Would love to hear how it went.

Thanks
Cat

Sent from my iPhone

Re: [EXTERNAL] RE: Request for Meeting Jan. 11th in the morning

From: "Robinson, Catherine" (b) (6) @pfizer.com>
To: "Melle, John M. EOP/USTR" <john_melle@ustr.eop.gov>
Date: Sun, 07 Jan 2018 17:01:03 -0500

Thanks John.

Sent from my iPhone

On Jan 6, 2018, at 2:17 PM, Melle, John M. EOP/USTR <John_Melle@ustr.eop.gov> wrote:

Hi Cat –

Not able to do this meeting – perhaps next visit?

John

From: Robinson, Catherine (b) (6) @pfizer.com]
Sent: Friday, January 5, 2018 10:32 AM
To: Melle, John M. EOP/USTR <John_Melle@ustr.eop.gov>
Subject: [EXTERNAL] RE: Request for Meeting Jan. 11th in the morning

Hi John

Following up to see if you are available to meet. Thanks, Cat

From: Robinson, Catherine
Sent: Wednesday, January 3, 2018 11:08 AM
To: 'Melle, John M. EOP/USTR'
Subject: Request for Meeting Jan. 11th in the morning

Hi John

Happy New Year! Hope you had a nice holiday and got some well-deserved time off!

Pfizer's Regional Vice President for Latin America-Om Arora- will be in DC on January 11th. Are you available to meet with him in the morning to discuss NAFTA, Mexico, Colombia and Argentina?

Thank you
Cat

[EXTERNAL] RE: Colombia-OECD

From: "Robinson, Catherine" (b) (6) @pfizer.com>
To: "O'Connor, Leslie C. EOP/USTR" <leslie_oconnor@ustr.eop.gov>, "Melle, John M. EOP/USTR" <john_melle@ustr.eop.gov>, "Shackleford, Dawn M. EOP/USTR" <dawn_shackleford@ustr.eop.gov>, "Sophos, Zoe M. EOP/USTR" <zoe_m_sophos@ustr.eop.gov>, "Morrow, Cara M. EOP/USTR" <cara_morrow@ustr.eop.gov>, "Whitlock, Joe P. EOP/USTR" <joseph_p_whitlock@ustr.eop.gov>
Date: Tue, 06 Mar 2018 12:20:54 -0500

Here is specific language from the regulation:

The second paragraph under Considerations on the first page states clearly "That the evaluation (carried out by IETS)will be requirements for the evaluation of the corresponding sanitary registration and/or its renewal."

From: Robinson, Catherine
Sent: Tuesday, March 6, 2018 11:57 AM
To: 'O'Connor, Leslie C. EOP/USTR'; Melle, John M. EOP/USTR; Shackleford, Dawn M. EOP/USTR; Sophos, Zoe M. EOP/USTR; Morrow, Cara M. EOP/USTR; Whitlock, Joe P. EOP/USTR
Subject: RE: Colombia-OECD

Thanks Leslie.

As you have probably heard, the Colombians finalized and published the regulation on article 72 today.

(b) (4)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Cat

From: O'Connor, Leslie C. EOP/USTR [mailto:Leslie_OConnor@ustr.eop.gov]
Sent: Monday, March 5, 2018 12:21 PM
To: Robinson, Catherine; Melle, John M. EOP/USTR; Shackleford, Dawn M. EOP/USTR; Sophos, Zoe M. EOP/USTR; Morrow, Cara M. EOP/USTR; Whitlock, Joe P. EOP/USTR
Subject: [EXTERNAL] RE: Colombia-OECD

Catherine, Please remember in the future to include Joe Whitlock on all Colombia-related emails. Adding him here.

From: Robinson, Catherine (b) (6) @pfizer.com]
Sent: Monday, March 5, 2018 12:04 PM
To: Melle, John M. EOP/USTR <John_Melle@ustr.eop.gov>; Shackleford, Dawn M. EOP/USTR

<Dawn_Shackleford@ustr.eop.gov>; O'Connor, Leslie C. EOP/USTR <Leslie_OConnor@ustr.eop.gov>;
Sophos, Zoe M. EOP/USTR <zoe_m_sophos@ustr.eop.gov>; Morrow, Cara M. EOP/USTR
<Cara_Morrow@ustr.eop.gov>
Subject: [EXTERNAL] RE: Colombia-OECD

Adding Cara. thanks

From: Robinson, Catherine
Sent: Monday, March 5, 2018 12:03 PM
To: 'Melle, John M. EOP/USTR'; 'Shackleford, Dawn M. EOP/USTR'; O'Connor, Leslie C. EOP/USTR;
'zoe_m_sophos@ustr.eop.gov'
Subject: Colombia-OECD

John, Dawn, Leslie and Zoe

I'm reaching out in advance of all the meetings this week with the Colombian Delegation. First, I want to thank you all for the letter from Amb. Lighthizer to Minister Gutierrez and your continued engagement on our issues.

Second, I wanted to convey our position. I just returned from Bogota. I was there last week as part of the Chamber delegation on the margins of the G2G meetings. As you can imagine the OECD was a topic of much interest from all sides. (b) (4)

[REDACTED]

On our three priorities here is what we would like the GoC to do in advance of the US supporting accession:

Article 72:

(b) (4)

[REDACTED]

IP: (b) (4)

Biologics:

(
b
)
(
4
)

I want to stress two recent developments:

1. The draft regs on article 72 (b) (4)
2. The Government of Malaysia is visiting with the Colombian Minister of Health in Bogota this week (while the Trade and Finance ministers are in DC) to discuss ways to adopt Colombia's DPI policy in Malaysia! (b) (4)

Thank you again and please let me know if you have any questions,
Cat

Catherine Robinson
Director, International Government Affairs
Pfizer Inc

(b) (6) @pfizer.com

(b) (6)

Re: [EXTERNAL] Time to chat re: OECD/CO?

From: "Robinson, Catherine" (b) (6) @pfizer.com>
To: "Sophos, Zoe M. EOP/USTR" <zoe_m_sophos@ustr.eop.gov>
Date: Wed, 04 Apr 2018 16:52:25 -0400

Thanks. Talk tomorrow.

Sent from my iPhone

On Apr 4, 2018, at 4:24 PM, Sophos, Zoe M. EOP/USTR <zoe_m_sophos@ustr.eop.gov> wrote:

Sounds great, thanks Catherine. How about 10am tomorrow? Unless there's a time you prefer, I'll plan to give you a call then.

Best,
Zoe

From: Robinson, Catherine (b) (6) @pfizer.com>
Sent: Wednesday, April 4, 2018 1:03 PM
To: Sophos, Zoe M. EOP/USTR <zoe_m_sophos@ustr.eop.gov>
Subject: RE: [EXTERNAL] Time to chat re: OECD/CO?

Thanks Zoe. Appreciate you reaching out. We met a few times a year or so ago. I was out on maternity leave for a while but have been engaged since the beginning on Colombia.

I'm generally open as well. Feel free to give me a call on my cell (b) (6)

Thanks, cat

From: Sophos, Zoe M. EOP/USTR [mailto:zoe_m_sophos@ustr.eop.gov]
Sent: Wednesday, April 4, 2018 11:41 AM
To: Robinson, Catherine
Subject: RE: [EXTERNAL] Time to chat re: OECD/CO?

Hi Catherine,

We may have met before, but my name is Zoe and I lead on the OECD Trade Committee for USTR. Cara forwarded me your email below, and I wanted to let you know I'd be happy to chat about Colombia if that's still of interest.

I'm relatively open this week – please just let me know if there are some times that might work for you.

Best,
Zoe

Zoe Sophos
Deputy Director for WTO & Multilateral Affairs
Office of the United States Trade Representative
zoe_m_sophos@ustr.eop.gov
Tel: 202-395-6129

Begin forwarded message:

From: "Robinson, Catherine" (b) (6) [REDACTED]@pfizer.com>
Date: April 3, 2018 at 2:02:31 PM EDT
To: "Morrow, Cara M. EOP/USTR" <Cara_Morrow@ustr.eop.gov>
Subject: [EXTERNAL] Time to chat re: OECD/CO?

Hi Cara

I just left you a VM. Looking to catch up quickly on Colombia when you have a minute. I'm open most of the rest of the day except for 3:15 to 4:30 or later this week. Thanks!

Catherine Robinson
Director, International Government Affairs
Pfizer Inc
(b) (6) [REDACTED]@pfizer.com
(b) (6) [REDACTED]
[REDACTED]

Re: [EXTERNAL] RE: Time for a quick chat?

From: "Robinson, Catherine" (b) (6) @pfizer.com>
To: "Sophos, Zoe M. EOP/USTR" <zoe_m_sophos@ustr.eop.gov>
Date: Fri, 20 Apr 2018 15:20:32 -0400

Thank you! We agree.

Sent from my iPhone

> On Apr 20, 2018, at 2:04 PM, Sophos, Zoe M. EOP/USTR <zoe_m_sophos@ustr.eop.gov> wrote:
>
> Hi Catherine,
>
> Thanks for reaching out. If you're curious about next week's Trade Committee meeting, Colombia has yet to achieve its outstanding commitments in the Trade Committee so we do not feel it will be possible for the committee to close its review next week.
>
> If it's about something else, just let me know!
>
> Best,
> Zoe
>
> -----Original Message-----
> From: Robinson, Catherine (b) (6) @pfizer.com>
> Sent: Friday, April 20, 2018 12:48 PM
> To: Sophos, Zoe M. EOP/USTR <zoe_m_sophos@ustr.eop.gov>
> Subject: [EXTERNAL] Time for a quick chat?
>
> I'm on my cell today (b) (6) Thanks
>
> Sent from my iPhone

[EXTERNAL] change in position

From: "Robinson, Catherine" (b) (6) @pfizer.com>
To: "Sophos, Zoe M. EOP/USTR" <zoe_m_sophos@ustr.eop.gov>
Date: Wed, 25 Apr 2018 10:18:36 -0400

Hi Zoe

I'm hearing that the USG has changed its position and will now support Colombia due to side letters that create enforcement for the trucking and copyright issues. What about the IP concerns for pharmaceuticals? If this is true that is a really bad precedent. Appreciate any details you can share. Much appreciated.

Thanks, Cat

Catherine Robinson
Director, International Government Affairs
Pfizer Inc

(b) (6) @pfizer.com

(b) (6)

(b) (6)