

From: [CVM Import Requests](#)
To: "Thomas Reidarson"; [CVM Import Requests](#)
Cc: [Charles Vinick](#)
Subject: RE: [EXTERNAL] Follow-up to my message
Date: Friday, December 2, 2022 9:07:02 AM
Attachments: [RE EXTERNAL Permission to obtain further shipments of Faropenem from the Maruho Company in Japan.msg](#)
[Faropenem 2022 and 2023 .pdf](#)

Dear Dr. Thomas Reidarson,

Attached is a revised letter which was sent to you on 11/28/22.

Sincerely,

(b) (6)

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance
Email: CVMImportRequests@fda.hhs.gov

-----Original Message-----

From: Thomas Reidarson <reidarsongroup@me.com>
Sent: Friday, December 2, 2022 8:46 AM
To: CVM Import Requests <CVMImportRequests@fda.hhs.gov>
Cc: Charles Vinick <cvinick@mac.com>
Subject: [EXTERNAL] Follow-up to my message

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello (b) (6)

I certainly do not disrupt your business, but I was hoping to be able to place the order for 17,000 tablets of Faropenem before this weekend. With the upcoming holidays I am afraid shipping from Japan to the United States may be slower than usual.

Thank you for any assistance you can provide us.

Kind regards,
Tom

Sent from my iPhone

From: CVM Import Requests []
To: 'Thomas Reidarson' [reidarsongroup@me.com]; CVM Import Requests [CVMImportRequests@fda.hhs.gov]
Subject: RE: [EXTERNAL] Permission to obtain further shipments of Faropenem from the Maruho Company in Japan
Date: Monday, November 28, 2022 10:43:15
Attachment 1: Faropenem 2022 and 2023 .pdf
Attachment 2: image001.png
Attachment 3: image002.jpg
Attachment 4: image003.jpg
Attachment 5: image004.jpg
Attachment 6: image005.jpg
Attachment 7: image006.jpg

Dear Dr. Thomas Reidarson,

Attached is a revised letter.

Sincerely,

(b) (6)

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov

<http://www.fda.gov/>

<https://www.facebook.com/FDA> https://twitter.com/US_FDA

<http://www.youtube.com/user/USFoodandDrugAdmin> <http://www.flickr.com/photos/fdaphotos/>

<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

From: Thomas Reidarson <reidarsongroup@me.com>;

Sent: Wednesday, November 23, 2022 1:14 PM

To: CVM Import Requests <CVMImportRequests@fda.hhs.gov>;

Cc: Charles Vinick <cvinick@mac.com>;

Subject: Re: [EXTERNAL] Permission to obtain further shipments of Faropenem from the Maruho Company in Japan

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello (b) (6) ,

Can we proceed with placing an order now so we can obtain another 30 day supply before we run out of Faropenem in 2 weeks?

Thank you in advance,

Tom

Sent from my iPhone

On Nov 21, 2022, at 5:56 PM, Thomas Reidarson <reidarsongroup@me.com> wrote:

Thank you (b) (6)

Thank you very much for your extremely quick response. Since we do not want to run short of Faropenem for Lolita I would like to apply for an additional shipment of 500 tablets and 3 boxes of 100 tablets, 200 mg tablets, for a total of 4800 tablets, to be ordered before December 2022. Is there any chance you can grant us an extension that enables us to order the same number of tablets, in increments of 4800, as needed in 2023 without having to request permission each time? If not, I am more than happy to submit a new application for each order.

We hope that the current order and even some of a second order for 2022 will be sufficient to halt the infection, but we want to be prepared in the event she relapses as she has in the past with other antibiotics. For this reason, we want to always be prepared for the worse case scenario that she gives us very little notice and we need to place her on at a moment's notice.

Thank you in advance for your help and further help for the future.

Kind regards,

Tom

<image.tiff>

Thomas Reidarson DVM, DACZM

<unknown.tiff>

(b) (6)

w. www.marineanimalspecialists.com www.reidarsongroup.com e. reidarsongroup@me.com skype. Reidarson location: San Diego, California, USA

On Nov 21, 2022, at 10:48 AM, CVM Import Requests <CVMImportRequests@fda.hhs.gov> wrote:

Dear Dr. Thomas Reidarson,

The current letter is for : 9 boxes of 500 tablets and 3 boxes of 100 tablets, 200mg tablets. Total 4800 tablets. If you have used this quantity than provide additional quantity estimate for 2022 and 2023. You can always import less quantity than listed in the letter.

Sincerely,

(b) (6)

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov

[<image001.png>](#)

[<image002.jpg>](#) [<image003.jpg>](#) [<image004.jpg>](#) [<image005.jpg>](#) [<image006.jpg>](#)

From: Thomas Reidarson <reidarsongroup@me.com>

Sent: Monday, November 21, 2022 11:58 AM

To: CVM Import Requests <CVMImportRequests@fda.hhs.gov>

Cc: Charles Vinick <cvinick@mac.com>

Subject: [EXTERNAL] Permission to obtain further shipments of Faropenem from the Maruho Company in Japan

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear (b) (6)

Thank you again for helping our team navigate through the acquisition of a 30-day supply of Faropenem from the Maruho company in Japan for Lolita, the killer whale from Miami Seaquarium. Once we figured out which Japanese company was producing Faropenem the process became easier after your spot-on instructions. Although it is early to be absolutely certain, we believe Lolita is improving and benefiting from this antibiotic. I have to say that the timing of acquisition could not have been better since we started her on it on the day it arrived in Miami. Well done to you and everyone involved!

The reason for this email is to begin the process of obtaining permission to purchase more Faropenem from the Maruho Company before the end of December, perhaps as early as December 7, 2022, and then obtain an open ended permit to purchase Faropenem beginning January 2023. My original calculation was to have enough for November 11 through December 10, 2022, but since we do not

whether this will provide a cure we want to be certain that we will have enough to get Lolita through at least another month. As you can imagine we need to feel comfortable that her chronic infection is sufficiently controlled to make the eventual decision to withdraw the antibiotic.

We are taking blood samples at four hour intervals over the first week of therapy in order to understand the pharmacokinetics of Faropenem in an animal that has never been treated with this antibiotic. Based on human treatment and one other smaller marine mammal we chose to give Faropenem every eight hours, however these studies will eventually guide treatment that may may lead his to change the dose or even dosing interval. Of course this would never be possible had we been unable to obtain Faropenem and it was your efforts that provided this opportunity.

Please tell me if you need any additional information to allow us to order more Faropenem for 2022 and then continue to obtain what is needed for Lolita for 2023.

Thank you again for your assistance.

Kind regards,

Tom

<image007.png>

Thomas Reidarson DVM, DACZM

<image008.png>

(b) (6)

w. www.marineanimalspecialists.com www.reidarsongroup.com e. reidarsongroup@me.com skype. Reidarson location:
San Diego, California, USA

<Faropenem 10-26-22.pdf>



November 23, 2022

Dear Dr. Thomas H. Reidarson:

This is in response to your email dated November 28, 2022, requesting permission to import Faropenem from Japan to treat a Killer Whale for a resistant bacterial infection. Center for Veterinary Medicine (CVM) reviewed your request and approving your request for two shipments of Faropenem of the following.

Quantity : 9 boxes of 500 tablets and 3 boxes of 100 tablets, 200mg tablets. Total 4800 tablets.

The drug will be supplied by: Maruho, 1-5-22, Nakatsu, Kita-ku, Osaka, Japan.

The drug will be imported by Thomas H. Reidarson, DVM, Dipl. ACZM (aquatic), consultant veterinarian for the Miami Seaquarium and CEO of Reidarson Group: Marine Animal Specialists

The drug will be used at Miami Seaquarium, 4400 Rickerbacker Causeway, Key Biscayne, Florida, 33149

This permission will expire on December 31, 2023. Should you need this or any other unapproved drug in the future, you must submit a separate request. **Attached this letter when importing Faropenem into the United States.**

If you have any questions, please call (b) (6) at (b) (6) or submit your request through CVMImportRequests@fda.hhs.gov.

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Sincerely,

(b) (6)

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov



Thank you again for providing us with the permission to import additional Faropenem antibiotic from the Maruho company in Japan. When we contacted them with the FDA per permit you provided they replied that they want to ship a single order of 17,000 tablets, and I believe that should be sufficient to get Lolita through this illness, at least in the short term. Maruho has today requested that the authorization letter be revised to state the new quantity will be 34 boxes of 500, 200 mg tablets, for a total of 17,000 tablets.

Based on how things are going with her current clinical condition, that at times has been precarious, we certainly want to have sufficient enough Faropenem on hand to get her through another crisis, should one occur. Each of us working with Lolita is grateful for your efforts and know that you and the FDA are contributing to her health needs.

Kind regards,

Tom

<image007.png>

Thomas Reidarson DVM, DACZM

<image008.png>

(b) (6)

w. www.marineanimalspecialists.com www.reidarsongroup.com e. reidarsongroup@me.com skype. Reidarson location: San Diego, California, USA

On Nov 28, 2022, at 9:43 AM, CVM Import Requests <CVMImportRequests@fda.hhs.gov> wrote:

Dear Dr. Thomas Reidarson,

Attached is a revised letter.

Sincerely,

(b) (6)

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov

<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

From: Thomas Reidarson <reidarsongroup@me.com>

Sent: Wednesday, November 23, 2022 1:14 PM

To: CVM Import Requests <CVMImportRequests@fda.hhs.gov>

Cc: Charles Vinick <cvinick@mac.com>

Subject: Re: [EXTERNAL] Permission to obtain further shipments of Faropenem from the Maruho Company in Japan

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello (b) (6),

Can we proceed with placing an order now so we can obtain another 30 day supply before we run out of Faropenem in 2 weeks?

Thank you in advance,
Tom

Sent from my iPhone

On Nov 21, 2022, at 5:56 PM, Thomas Reidarson <reidarsongroup@me.com> wrote:

Thank you (b) (6)

Thank you very much for your extremely quick response. Since we do not want to run short of Faropenem for Lolita I would like to apply for an additional shipment of 500 tablets and 3 boxes of 100 tablets, 200 mg tablets, for a total of 4800 tablets, to be ordered before December 2022. Is there any chance you can grant us an extension that enables us to order the same number of tablets, in increments of 4800, as needed in 2023 without having to request permission each time? If not, I am more than happy to submit a new application for each order.

We hope that the current order and even some of a second order for 2022 will be sufficient to halt the infection, but we want to be prepared in the event she relapses as she has in the past with other antibiotics. For this reason, we want to always be prepared for the worse case scenario that she gives us very little notice and we need to place her on at a moment's notice.

Thank you in advance for your help and further help for the future.

Kind regards,

Tom

<image.tiff>

Thomas Reidarson DVM, DACZM

<unknown.tiff>

(b) (6)

w. www.marineanimalspecialists.com www.reidarsongroup.com e. reidarsongroup@me.com skype. Reidarson location: San Diego, California, USA

From: [CVM Import Requests](#)
To: "Thomas Reidarson"; [CVM Import Requests](#)
Subject: RE: [EXTERNAL] Fwd: Importing an Unapproved Drug for Research Purposes...
Date: Wednesday, October 5, 2022 3:58:33 PM
Attachments: [image001.png](#)
[image002.jpg](#)
[image003.jpg](#)
[image004.jpg](#)
[image005.jpg](#)
[image006.jpg](#)
[image007.png](#)
[image008.png](#)

Dear Dr. Thomas H. Reidarson:

This is in response to your email dated Octo 4, 2022 requesting permission to import Faropenem from Japan to treat a Killer Whale for a resistant bacterial infection. Center for Veterinary Medicine (CVM) reviewed your request and approving your request for less than a 90-day supply of Faropenem.

Quantity : 400 boxes each containing 12, 200 mg tablets

The drug will be supplied by: Daiichi Sankyo Co., LTD. (TSE 4568), 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, 103-8426, Japan

The drug will be imported by Thomas H. Reidarson, DVM, Dipl. ACZM (aquatic), consultant veterinarian for the Miami Seaquarium and CEO of Reidarson Group: Marine Animal Specialists

The drug will be used at Miami Seaquarium, 4400 Rickerbacker Causeway, Key Biscayne, Florida, 33149

This permission will expire on December 31, 2022. Should you need this or any other unapproved drug in the future, you must submit a separate request. **Attached this letter when importing Faropenem into the United States.**

If you have any questions, please call (b) (6) at (b) (6) or submit your request through CVMImportRequests@fda.hhs.gov.

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Sincerely,

(b) (6)

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov

U.S. Food and Drug Administration



From: Thomas Reidarson <reidarsongroup@me.com>

Sent: Wednesday, October 5, 2022 12:46 PM

To: CVM Import Requests <CVMImportRequests@fda.hhs.gov>

Subject: Re: [EXTERNAL] Fwd: Importing an Unapproved Drug for Research Purposes...

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello (b) (6),

Please excuse my tardiness in getting this to you.

The U.S address in the US is:

Daiichi Sankyo

211 Mt Airy Road

Basking Ridge, NJ 07920

Tel: 973-944-2600

Parent Company:

Daiichi Sankyo Co., LTD. (TSE 4568)

3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo

103-8426, Japan

Phone: +81-3-6225-1111

daiichisankyo.com

Thanks in advance,

Tom

Sent from my iPhone

On Oct 4, 2022, at 4:35 PM, CVM Import Requests
<CVMImportRequests@fda.hhs.gov> wrote:

Dear Dr. Thomas H. Reidarson:

Thanks. Please provide the address of manufacturer and supplier. Thanks.

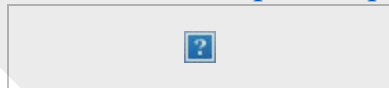
Sincerely,

(b) (6)

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov



From: Thomas Reidarson <reidarsongroup@me.com>

Sent: Tuesday, October 4, 2022 4:24 PM

To: CVM Import Requests <CVMImportRequests@fda.hhs.gov>

Subject: Re: [EXTERNAL] Fwd: Importing an Unapproved Drug for Research Purposes...

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

I apologize for not including the address. It is:

Miami Seaquarium

From: [CHARLES VINICK](#)
To: [CVM Import Requests](#)
Cc: [Tom Reidarson](#)
Subject: Re: [EXTERNAL] Faropenem
Date: Wednesday, October 26, 2022 12:35:49 PM

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear (b) (6)

On behalf of Dr. Reidarson and myself, thank you very much for your prompt response to our request. It is very helpful. I have sent the revised authorization to Maruho in Japan and look forward to having them move forward expeditiously.

Thank you again and my best regards,
Charles

Charles Vinick
Friends of Lolita
805-252-5421
cvinick@mac.com

On Oct 26, 2022, at 6:58 AM, CVM Import Requests
<CVMImportRequests@fda.hhs.gov> wrote:

Dear Charles Vinick:
Revised letter is attached.
Sincerely,

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov

[<image001.png>](#)

[<image002.jpg>](#) [<image003.jpg>](#) [<image004.jpg>](#) [<image005.jpg>](#) [<image006.jpg>](#)

From: CHARLES VINICK <cvinick@mac.com>

Sent: Tuesday, October 25, 2022 10:03 PM

To: CVM Import Requests <CVMImportRequests@fda.hhs.gov>

Cc: Tom Reidarson <reidarsongroup@me.com>

Subject: [EXTERNAL] Re: Faropenem

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear (b) (6)

Thank you again for granting us this (b) (4). My colleague, Dr. Thomas Reidarson, is in Curacao this evening with limited email connectivity. We have today received a positive response from Maruho for our request to import Faropenem. Their packaging of Faropenem is different than what is stated (b) (4) and they have a concern that

the wording in (b) (4) may cause a delay in customs.

On behalf of Dr. Reidarson, I respectfully ask if you can revise the quantity statement in your letter of October 12, 2022 (attached) to read:

Quantity: 9 boxes of 500 tablets and 3 boxes of 100 tablets, 200mg tablets. Total 4800 tablets.

We look forward to completing the order with Maruho on Wednesday, October 26 if possible. Please do not hesitate to call me on 805-252-5421, if there is anything I can do to facilitate this request.

Thank you.

Respectfully,

Charles

Charles Vinick

on behalf of Dr. Thomas Reidarson

Friends of Lolita

805-252-5421

cvinick@mac.com

On Oct 11, 2022, at 7:58 AM, CVM Import Requests
<CVMImportRequests@fda.hhs.gov> wrote:

Dear Dr. Thomas H. Reidarson:

Please see attached letter.

Sincerely,

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov

[<image001.png>](#)

[<image002.jpg>](#) [<image003.jpg>](#) [<image004.jpg>](#) [<image005.jpg>](#) [<image006.jpg>](#)

From: Thomas Reidarson <reidarsongroup@me.com>

Sent: Sunday, October 9, 2022 4:37 PM

To: CVM Import Requests <CVMImportRequests@fda.hhs.gov>

Cc: Charles Vinick <cvinick@mac.com>

Subject: Re: [EXTERNAL] Importing an Unapproved Drug for Research Purposes...

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello (b) (6)

Thank you again for granting us (b) (4) My colleague, Charles Vinick who is purchasing the Faropenem, is having trouble convincing his Japanese contact for Daiichi Sankyo Co., LTD that this truly is a legitimate (b) (4) Faropenem. I'm sorry to ask, but is it possible to provide us with a permit to import this antibiotic either in a PDF form or some other form

that is not an email? We believe the Japanese are having trouble accepting an email and may need a more official appearing document. I apologize for prolonging this process, but it is vital that we acquire this as soon as humanly possible.

Kind regards,

Tom

<image007.png>

Thomas Reidarson DVM, DACZM

<image008.png>

(b) (6)

w. www.marineanimalspecialists.com www.reidarsongroup.com e. reidarsongroup@me.com skype. Reidarson location: San Diego, California, USA

On Oct 5, 2022, at 3:58 PM, CVM Import Requests
<CVMImportRequests@fda.hhs.gov> wrote:

Dear Dr. Thomas H. Reidarson:

This is in response to your email dated Oct 4, 2022 requesting permission to import Faropenem from Japan to treat a Killer Whale for a resistant bacterial infection. Center for Veterinary Medicine (CVM) reviewed your request and approving your request for less than a 90-day supply of Faropenem.

Quantity : 400 boxes each containing 12, 200 mg tablets

The drug will be supplied by: Daiichi Sankyo Co., LTD.
(TSE 4568), 3-5-1, Nihonbashi-honcho, Chuo-ku,
Tokyo, 103-8426, Japan

The drug will be imported by Thomas H. Reidarson, DVM, Dipl. ACZM (aquatic), consultant veterinarian for the Miami Seaquarium and CEO of Reidarson Group: Marine Animal Specialists

The drug will be used at Miami Seaquarium, 4400 Rickerbacker Causeway, Key Biscayne, Florida, 33149

This permission will expire on December 31, 2022. Should you need this or any other unapproved drug in the future, you must submit a separate request. **Attached this letter when importing Faropenem into the United States.**

If you have any questions, please call (b) (6) or submit your request through CVMImportRequests@fda.hhs.gov.

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily

represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Sincerely,

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov

[<image001.png>](#)

[<image002.jpg>](#) [<image003.jpg>](#) [<image004.jpg>](#) [<image005.jpg>](#)

[<image006.jpg>](#)

From: Thomas Reidarson <reidarsongroup@me.com>

Sent: Wednesday, October 5, 2022 12:46 PM

To: CVM Import Requests

<CVMImportRequests@fda.hhs.gov>

Subject: Re: [EXTERNAL] Fwd: Importing an Unapproved Drug for Research Purposes...

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello (b) (6)

Please excuse my tardiness in getting this to you.

The U.S address in the US is:

Daiichi Sankyo

211 Mt Airy Road

Basking Ridge, NJ 07920

Tel: 973-944-2600

Parent Company:

Daiichi Sankyo Co., LTD. (TSE 4568)

3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo

103-8426, Japan

Phone: +81-3-6225-1111

daiichisankyo.com

Thanks in advance,

Tom

Sent from my iPhone

On Oct 4, 2022, at 4:35 PM, CVM Import Requests <CVMImportRequests@fda.hhs.gov> wrote:

Dear Dr. Thomas H. Reidarson:

Thanks. Please provide the address of manufacturer and supplier. Thanks.

Sincerely,

(b) (6)

FDA/CVM/OSC/Division of Drug
Compliance

Email:

CVMImportRequests@fda.hhs.gov

[<image001.png>](#)

[<image002.jpg>](#) [<image003.jpg>](#) [<image004.jpg>](#)

[<image005.jpg>](#) [<image006.jpg>](#)

From: Thomas Reidarson

[<reidarsongroup@me.com>](mailto:reidarsongroup@me.com)

Sent: Tuesday, October 4, 2022 4:24 PM

To: CVM Import Requests

[<CVMImportRequests@fda.hhs.gov>](mailto:CVMImportRequests@fda.hhs.gov)

Subject: Re: [EXTERNAL] Fwd: Importing an
Unapproved Drug for Research Purposes...

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

I apologize for not including the address. It is:

Miami Seaquarium

4400 Rickerbacker Causeway

Key Biscayne, Florida

33149

Kind regards,

Tom

Sent from my iPhone

On Oct 4, 2022, at 3:59 PM, CVM
Import Requests

[<CVMImportRequests@fda.hhs.gov>](mailto:CVMImportRequests@fda.hhs.gov) wrote:

Dear Dr. Thomas H. Reidarson:

Please provide the address it
will be delivered, manufacturer
and supplier address. Thanks.

Sincerely,

(b) (6)

FDA/CVM/OSC/Division
of Drug Compliance

Email:

CVMImportRequests@fda.hhs.gov

[<image001.png>](#)

[<image002.jpg>](#) [<image003.jpg>](#)

[<image004.jpg>](#) [<image005.jpg>](#)

[<image006.jpg>](#)

From: Thomas Reidarson

[<reidarsongroup@me.com>](mailto:reidarsongroup@me.com)

Sent: Tuesday, October 4, 2022

3:07 PM

To: CVM Import Requests

[<CVMImportRequests@fda.hhs.gov>](mailto:CVMImportRequests@fda.hhs.gov)

Cc: Travis Burke

[<tburke@thedolphinco.com>](mailto:tburke@thedolphinco.com);

Charles Vinick

[<cvinick@mac.com>](mailto:cvinick@mac.com)

Subject: [EXTERNAL] Fwd:

Importing an Unapproved Drug
for Research Purposes...

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear (b) (6),

Thank you for your attention to our need to acquire Faropenem, an oral Carbopenem antibiotic not available in the United States, to only be used with Lolita, a 57-year-old female killer whale (*Orcinus orca*) residing at the Miami Sea Aquarium in Miami Florida, USA. I hope I adequately addressed your inquiries in the italicized text below. Should you need more information or have further questions please do not hesitate to contact me at any time.

Kind regards,

Tom

From: CVM Import Requests []
To: 'Thomas Reidarson' [reidarsongroup@me.com]; CVM Import Requests [CVMImportRequests@fda.hhs.gov]
Subject: RE: [EXTERNAL] Fwd: Importing an Unapproved Drug for Research Purposes...
Date: Wednesday, October 05, 2022 15:58:29
Attachment 1: image001.png
Attachment 2: image002.jpg
Attachment 3: image003.jpg
Attachment 4: image004.jpg
Attachment 5: image005.jpg
Attachment 6: image006.jpg
Attachment 7: image007.png
Attachment 8: image008.png

Dear Dr. Thomas H. Reidarson:

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Quantity : 400 boxes each containing 12, 200 mg tablets

The drug will be supplied by: Daiichi Sankyo Co., LTD. (TSE 4568), 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, 103-8426, Japan

The drug will be imported by Thomas H. Reidarson, DVM, Dipl. ACZM (aquatic), consultant veterinarian for the Miami Seaquarium and CEO of Reidarson Group: Marine Animal Specialists

The drug will be used at Miami Seaquarium, 4400 Rickerbacker Causeway, Key Biscayne, Florida, 33149

This permission will expire on December 31, 2022. Should you need this or any other unapproved drug in the future, you must submit a separate request. **Attached this letter when importing Faropenem into the United States.**

If you have any questions, please call (b) (6) or submit your request through CVMImportRequests@fda.hhs.gov.

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Sincerely,

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov

<http://www.fda.gov/>
<https://www.facebook.com/FDA> https://twitter.com/US_FDA
<http://www.youtube.com/user/USFoodandDrugAdmin> <http://www.flickr.com/photos/fdaphotos/>
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

From: Thomas Reidarson <reidarsongroup@me.com>
Sent: Wednesday, October 5, 2022 12:46 PM
To: CVM Import Requests <CVMImportRequests@fda.hhs.gov>
Subject: Re: [EXTERNAL] Fwd: Importing an Unapproved Drug for Research Purposes...

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello (b) (6)

Please excuse my tardiness in getting this to you.

The U.S address in the US is:

Daiichi Sankyo
211 Mt Airy Road
Basking Ridge, NJ 07920
Tel: 973-944-2600

Parent Company:
Daiichi Sankyo Co., LTD. (TSE 4568)
3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo
103-8426, Japan
Phone: +81-3-6225-1111
daiichisankyo.com

Thanks in advance,

Tom

Sent from my iPhone

On Oct 4, 2022, at 4:35 PM, CVM Import Requests <CVMImportRequests@fda.hhs.gov> wrote:

Dear Dr. Thomas H. Reidarson:

Thanks. Please provide the address of manufacturer and supplier. Thanks.

Sincerely,

(b) (6)

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov

<http://www.fda.gov/>

<https://www.facebook.com/FDA>

https://secure-web.cisco.com/1KZhpmY1uBDwKK_jJxj8F2KXelymlpLoMzu-vH36Yiq2Tg5KWaw49W8VqC1tHDGKT0HDjWzXVYVMUn0LNOKVX7z9459ALp8CR_m99X6KaZSJAjnl-wFmSTq4dWkgPwRF9S6SUKFL0sWlxEu4XB6MnOw83fTpcnNXPd3dkEP6LSS6LX337EECwTwZbj32bVVJ9FYt9DmluvTkV3z-M-kQ/https%3A%2F%2Ftwitter.com%2FUS_FDA <http://www.youtube.com/user/USFoodandDrugAdmin>

[http://secure-web.cisco.com/19iZ8c2-p0LMEaJGBE5ZZrosXNJDW4THDOMc7ItndTwa1m0v1w4OBpjNGaZyrXqz1hrkzJ6u24ph0NvkXVH7a9LXLk84nA8VLZGRLjifvq2jSabn6KMScLuz1653N7HjtwCT4J4L9kzSjtKq8tgc8KU-E1DHjiPi4QUusiQYPSAa50L5Uolj3mgblSokmR-xrWqUZ4VWr4GjJ0ukRsd-g/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F](https://secure-web.cisco.com/19iZ8c2-p0LMEaJGBE5ZZrosXNJDW4THDOMc7ItndTwa1m0v1w4OBpjNGaZyrXqz1hrkzJ6u24ph0NvkXVH7a9LXLk84nA8VLZGRLjifvq2jSabn6KMScLuz1653N7HjtwCT4J4L9kzSjtKq8tgc8KU-E1DHjiPi4QUusiQYPSAa50L5Uolj3mgblSokmR-xrWqUZ4VWr4GjJ0ukRsd-g/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F)

<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

From: Thomas Reidarson <reidarsongroup@me.com>;

Sent: Tuesday, October 4, 2022 4:24 PM

To: CVM Import Requests <CVMImportRequests@fda.hhs.gov>;

Subject: Re: [EXTERNAL] Fwd: Importing an Unapproved Drug for Research Purposes...

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

I apologize for not including the address. It is:

Miami Seaquarium
4400 Rickerbacker Causeway
Key Biscayne, Florida
33149

Kind regards,
Tom

Sent from my iPhone

On Oct 4, 2022, at 3:59 PM, CVM Import Requests <CVMImportRequests@fda.hhs.gov> wrote:

Dear Dr. Thomas H. Reidarson:

Please provide the address it will be delivered, manufacturer and supplier address. Thanks.

Sincerely,

(b) (6)

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov

<http://www.fda.gov/>

<https://www.facebook.com/FDA>

https://secure-web.cisco.com/1i8dmlyV3ABJMAQrC41FpR7d5h7Z9ZYUlfOYmm9x6uXSojFV707D5mF4o6-NQ1GSnnrkYe0yQ6zKuLTzMzbQck8ZXAwvA7ICWYC9a0U_G_R6TcHTYa-tJTeHcHC0iYV4RqB6tOxyvmMbz2OHuyROTyORGLBZg7Elv-xP1i4DdCwIRG_GbUXsRF6Bf946z2s6r/https%3A%2F%2Ftwitter.com%2FUS_FDA <http://www.youtube.com/user/USFoodandDrugAdmin>
https://secure-web.cisco.com/1ImAlsCYzJK67CP2sPeJk2Dq2KhAbTFglabR7TfW5qMAfg0kTqM3wQCYepkaTu7CLsEtrI1QqaZf5X6Q95ta7Wk5hgVyeeraDVPJTbSJM-yBreG-sP1YOEIFI21FA_7IKAA8vnWoBhqBbQSLRmal0TSMtP3XGYzIYh5N0bkggzCw33QSV-5pBtHQb31D0GY78/http%3A%2F%2Fwww.flickr.com%2Fphoto%2Ffdaphotos%2F <http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

From: Thomas Reidarson <reidarsongroup@me.com>;

Sent: Tuesday, October 4, 2022 3:07 PM

To: CVM Import Requests <CVMImportRequests@fda.hhs.gov>;

Cc: Travis Burke <tburke@thedolphinco.com>; Charles Vinick <cvinick@mac.com>;

Subject: [EXTERNAL] Fwd: Importing an Unapproved Drug for Research Purposes...

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear (b) (6)

Thank you for your attention to our need to acquire Faropenem, an oral Carbopenem antibiotic not available in the United States, to only be used with Lolita, a 57-year-old female killer whale (*Orcinus orca*) residing at the Miami Sea Aquarium in Miami Florida, USA. I hope I adequately addressed your inquiries in the italicized text below. Should you need more information or have further questions please do not hesitate to contact me at any time.

Kind regards,

Tom

Thomas Reidarson DVM, DACZM

(b) (6)

w. www.marineanimalsspecialists.com www.reidarsongroup.com e. reidarsongroup@me.com skype. Reidarson location: San Diego, California, USA

Begin forwarded message:

From: CVM Import Requests <CVMImportRequests@fda.hhs.gov>;

Subject: RE: Importing an Unapproved Drug for Research Purposes...

Date: September 29, 2022 at 2:33:49 PM EDT

To: "reidarsongroup@me.com" <reidarsongroup@me.com>

Cc: AskOSC <AskOSC@fda.hhs.gov>

Dear Dr. Thomas H. Reidarson:

Thank you for your inquiry regarding the import of Faropenem. The Center for Veterinary Medicine (CVM) allows import of unapproved drugs under Personal Importation Policy (PIP). The veterinarians can submit this information to CVMImportRequests@fda.hhs.gov for review and approval before ordering this medicine.

The following links provides information on PIP:

<https://www.fda.gov/industry/import-basics/personal-importation>

The following criteria are to be met:

1. a serious/life-threatening illness exists; *Lolita is experiencing severe pneumonia likely from an ESBL E. coli, MDR Pseudomonas aeruginosa, and possible MRSA.*
2. the imported quantity does not exceed a 90-day supply; *We plan to only order enough Faropenem for 30 days*
3. there is no approved treatment available in the U.S.; and
4. the drug is not considered to be an unreasonable risk. *Faropenem is only available China, Japan, and India. (b) (4) and has treated several animals with it without any untoward effects*

The following documentation should be provided, if applicable, at the time of entry for review by FDA:

1. name of drug and drug class or family; *Faropenem in the class of Carbopenems*
2. name and address of the drug supplier; *Daiichi Sankyo located in Japan*
3. legal status of the drug in the country from which it is being imported; *Available to medical professions in China, Japan, and India*
4. written affirmation by the importer stating the drug is for personal use, and the imported quantity does not exceed a 90-day supply; *Faropenem is only to be administered at 3 mg/kg orally three times a day for the 57 year old killer whale named Lolita residing at the Miami Sea Aquarium*
5. Quantity of the drug. *400 boxes, each containing 12, 200 mg tablets*
6. statement that the drug is not FDA-approved for the intended use; *Faropenem is being used off label for compassionate use in a marine mammal*
7. statement that no FDA-approved drug is currently available that could be used as labeled or in an extra-label manner for the intended use; *Faropenem is not available by any pharmaceutical company in the United States.*
8. name of the veterinarian responsible for the treatment, vet facility's name, address, and phone number; *Thomas H. Reidarson, DVM, Dipl. ACZM (aquatic), consultant veterinarian for the Miami Sea Aquarium and CEO of Reidarson Group: Marine Animal Specialists*
9. the reason why an approved human or animal drug will not treat this disease or condition; *Following extensive blood and respiratory exudate cultures with sensitivities we have*

discovered there are no oral antimicrobials that are capable to treating her infections. Over the past 8 months we have used aminoglycosides and third generation injectable cephalosporins with variable results. She is currently on Meropenem, an injectable carbopenem and hope to be able to transition her from Meropenem to Faropenem once we receive the latter.

10. a statement (a) that you (the veterinarian) will notify the animal owner the drug is not approved; (b) that the drug will not be used in any food animal; (c) and that you agree to notify the FDA if there are adverse reactions. *I have already informed the owner of Lolita, Dolphin Company, that Faropenem will be given off label and not approved in marine mammals. The company understands that marine mammals are not considered food animals and have agreed to allow me to notify the FDA of any adverse effects. Dolphin Company is willing to assume the risk and understand the need to acquire an oral Carbopenem alternative.*

If you have additional questions regarding this specific inquiry, please submit to my attention through CVMImportRequests@fda.hhs.gov.

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Sincerely,

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance
Email: CVMImportRequests@fda.hhs.gov

-----Original Message-----

From: Thomas Reidarson <reidarsongroup@me.com>
Sent: Tuesday, September 27, 2022 5:47 PM
To: Ask CVM <AskCVM@fda.hhs.gov>
Subject: [EXTERNAL] (b) (4) for a killer whale

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

To whom it concerns,

I would like to look into acquiring (b) (4) for the compassionate use of an antibiotic, named Faropenem, that is only available in mainland China, Japan, and India.

I am the contract veterinarian for the Miami Sea Aquarium in Miami Florida and one of two primary caretakers for a 57-year-old killer whale named Lolita. We are currently battling an MDR E. coli and Pseudomonas aeruginosa pulmonary infection where each bacterium is only

sensitive to Amikacin and third generation cephalosporins, respectively, and both sensitive to carbopenems.

We just began using IV Meropenem and would like to be able to switch to the oral carbopenem, Faropenem. Since it is currently not available in the United States my contact in mainland China, (b) (6), from a large oceanarium is able to arrange acquisition from a local pharmaceutical company and mailing to the United States.

Faropenem comes in 200 mg tablets and will be dosed at 3 mg/kg PO TID. Lolita is 3600 kg, so we would like to acquire a 30 day supply or 4800, 200 mg tablets (400 boxes). We have a customs broker in Miami that can handle the receipt of the medication.

We appreciate any help you may be able to provide to help this killer whale.

Kind regards,

Tom

Thomas H. Reidarson DVM, Dipl. ACZM (aquatic) CEO Reidarson Group: Marine Animal Specialists LLC
952 I Avenue, Coronado California 92118, phone: (b) (6)

Sent from my iPhone



Memorandum

October 11, 2022

Dear Dr. Thomas H. Reidarson:

This is in response to your email dated Octo 4, 2022 requesting permission to import Faropenem from Japan to treat a Killer Whale for a resistant bacterial infection. Center for Veterinary Medicine (CVM) reviewed your request and approving your request for less than a 90-day supply of Faropenem.

Quantity : 400 boxes each containing 12, 200 mg tablets

The drug will be supplied by: Daiichi Sankyo Co., LTD. (TSE 4568), 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, 103-8426, Japan

The drug will be imported by Thomas H. Reidarson, DVM, Dipl. ACZM (aquatic), consultant veterinarian for the Miami Seaquarium and CEO of Reidarson Group: Marine Animal Specialists

The drug will be used at Miami Seaquarium, 4400 Rickerbacker Causeway, Key Biscayne, Florida, 33149

This permission will expire on December 31, 2022. Should you need this or any other unapproved drug in the future, you must submit a separate request. **Attached this letter when importing Faropenem into the United States.**

If you have any questions, please call (b) (6) or submit your request through CVMImportRequests@fda.hhs.gov.

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Sincerely,

(b) (6)

FDA/CVM/OSC/Division of Drug Compliance

Email: CVMImportRequests@fda.hhs.gov

Themed Reality