**From:** "Martha M. Rumore" <mrumore@frierlevitt.com>
**Sent:** Fri 12/4/2020 10:45:25 PM (UTC)
**To:** Abbie Divilio <AbbieD@Safechain.com>, Charles Boyd <CharlesB@Safechain.com>
**Subject:** RE: [EXTERNAL]RE: [EXTERNAL]RE: Gilead - Biktarvy information
**Attachment:** Gilead Letter - Mark up.docx

Hi Charlie and Abbie:

The point of asking for their FDA records is exactly that. They failed to do what they were required to do. Once they made a determination the product was illegitimate, they had 24 hours to notify FDA and their trading partners of that. The fact the failed to do so, does not place the burden on you (which they are attempting to do). However, I can remove that wording from both paragraphs.

I reworded the section about the third party manufacturers. Gilead needed to investigate and check back with their manufacturers. Just letting them know that you are aware of this. But we can remove this language as well.

As far as not supplying the T3 we can 1) acknowledge that the invoice they already have is correct; 2) refuse to provide for the reason you mentioned, 3) state that you purchased from an authorized trading partner (I'm assuming Gentek has a wholesale license), or we can indicate the license number of your supplier is listed in the FDA database of authorized wholesalers (I am sure you checked this already) and see what happens.
My thinking is while your obligation is to supply T3 is downstream, Gilead can actually obtain that information from White Cross Pharmacy. Not sure how you want to handle.

I can hop on a call Monday if you want to discuss further.

Best,
Martha

Martha M. Rumore, PharmD, MS, JD, LLM
*Senior Counsel*

FRIER LEVITT
ATTORNEYS AT LAW

101 Greenwich Avenue
Suite 8B
New York, NY 10006
(646) 970-3226 (direct)
(646) 970-2711 (office)
(973) 618-0650 (fax)
mrumore@frierlevitt.com
www.frierlevitt.com

GOVERNMENT EXHIBIT
205
1:24-cr-20255-WPD

New Jersey Office
84 Bloomfield Avenue
Pine Brook, NJ 07058

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**From:** Abbie Divilio <AbbieD@Safechain.com>
**Sent:** Friday, December 4, 2020 4:07 PM
**To:** Martha M. Rumore <mrumore@frierlevitt.com>; Charles Boyd <CharlesB@Safechain.com>
**Subject:** [EXTERNAL]RE: [EXTERNAL]RE: Gilead - Biktarvy information

Good afternoon Martha,
I have attached the letter with some comments and clarification in bold blue. Charlie and I chatted a bit about this today and had a few other comments we would like your feedback on:

- Do we really want to request a copy of their FDA records when it is likely there will not be any? What obligation will that hold us to? Additional reporting?
- We have no previous knowledge that their drugs are manufactured by a third party, is this valuable to reference?

We would prefer not to include a copy of the T3 exposing our vendors without their consent. How can we approach that?

Thank you and have a nice weekend!

**Abbie Divilio** | Director of Compliance
Safe Chain Solutions, LLC
822 Chesapeake Drive | Cambridge, MD 21613
office: 855.437.5727 x1017 | fax: 866.930.1128
www.SafeChain.com | LinkedIn

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**From:** Martha M. Rumore <mrumore@frierlevitt.com>

**Sent:** Friday, December 4, 2020 1:05 PM
**To:** Charles Boyd <CharlesB@Safechain.com>
**Cc:** Abbie Divilio <AbbieD@Safechain.com>
**Subject:** RE: [EXTERNAL]RE: Gilead - Biktarvy information

Hi Charlie:

Attached please find the Draft Letter to Gilead. Let me know if you want to discuss and/or send me an email with comments or if OK to send. I have a Client Hearing from 3-4 but am free other times.

Best,

Martha

Martha M. Rumore, PharmD, MS, JD, LLM
*Senior Counsel*

FRIER LEVITT
ATTORNEYS AT LAW

101 Greenwich Avenue
Suite 8B
New York, NY 10006
(646) 970-3226 (direct)
(646) 970-2711 (office)
(973) 618-0650 (fax)
mrumore@frierlevitt.com
www.frierlevitt.com

New Jersey Office
84 Bloomfield Avenue
Pine Brook, NJ 07058

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**From:** Charles Boyd <CharlesB@Safechain.com>
**Sent:** Friday, December 4, 2020 10:06 AM
**To:** Martha M. Rumore <mrumore@frierlevitt.com>
**Cc:** Abbie Divilio <AbbieD@Safechain.com>
**Subject:** [EXTERNAL]RE: Gilead - Biktarvy information

Hi Martha,

I just wanted to follow up on this since they requested a response by Monday. Please let us know if you have any questions. Thanks!

Charlie

**Charlie Boyd** | Founder & CEO
Safe Chain Solutions, LLC
822 Chesapeake Drive | Cambridge, MD 21613
office: 855.437.5727 | Cell: 301.875.1581
www.SafeChain.com | LinkedIn

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**From:** Charles Boyd
**Sent:** Wednesday, November 25, 2020 3:38 PM
**To:** Martha M. Rumore <mrumore@frierlevitt.com>
**Cc:** Abbie Divilio <AbbieD@Safechain.com>
**Subject:** FW: Gilead - Biktarvy information
**Importance:** Low

**Charlie Boyd** | Founder & CEO
Safe Chain Solutions, LLC
822 Chesapeake Drive | Cambridge, MD 21613
office: 855.437.5727 | Cell: 301.875.1581
www.SafeChain.com | LinkedIn

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**From:** Abbie Divilio <AbbieD@Safechain.com>
**Sent:** Wednesday, November 25, 2020 3:30 PM
**To:** Charles Boyd <CharlesB@Safechain.com>
**Subject:** Gilead - Biktarvy information
**Importance:** Low

Good afternoon,
After sorting through various emails and information I believe we have three things going on here. 1.)White Cross pharmacy has dispensed a bottle of Biktravy (lot CCXKVA) which is in question by Gilead and was sold by us. 2.) We inquired about Biktarvy (lot CCPDPA) to verify in August because someone complained about the packaging. 3.) We inquired about Biktarvy (Lot CDGXKA) in October, while we attempted to verify the T3 and expiration date.
Biktarvy (lot CCPDPA) was verified to be a legitimate product by Gilead in August (8/19/20) CB responded that we were investigating a customer complaint (White cross claimed this bottle contained Seroquel ER 300), which is the attachment entitled 'Biktarvy lot CCPDA complaint convo'

In early October (10/6/2020) we attempted to verify a transaction on the T3, Rochester Drug from Gilead. We were unable to because RD is closed, we had the conversation in 'Biktarvy CDGXKA information' We were attempting to verify this product because it was sold in 2018. We were looking for some information regarding expiration date and trying to understand the validity of the T3s we had received since some of the drugs were purchased over 2 years ago.

After reviewing our records, I do not see any conversations related to the lot number (CCXKVA) which is referenced in the letter from Gilead. I only see that the of the two lots we inquired about, one was verified and one was inconsistent with their records.

Let me know if you need additional information. I have had Dakota start to pull the T3s together as well. This situation and lot numbers do NOT address the issue with Biktarvy and WW customer Medicine Shoppe, which is the other customer we have taken a return for.

**Abbie Divilio** | Director of Compliance
Safe Chain Solutions, LLC
822 Chesapeake Drive | Cambridge, MD 21613
office: 855.437.5727 x1017 | fax: 866.930.1128
www.SafeChain.com | LinkedIn

FRIER LEVITT
ATTORNEYS AT LAW

**Martha M. Rumore,**
**Pharm.D., Esq.**
direct: 646.970.3226
mrumore@frierlevitt.com

December 4, 2020

***VIA EMAIL*: *Peter.colosi@gilead.com***

Peter M. Colosi
Senior Counsel, Anti-Counterfeiting
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

RE: Your November 23, 2020 Letter to Safe Chain Solutions, LLC

Dear Mr. Colosi:

We represent Safe Chain Solutions, LLC and are in receipt of your letter of November 23, 2020 to their Legal Department.. You requested a response no later than December 7, 2020. This correspondence serves as that response.

Your letter states two reasons for writing to Safe Chain Solutions: (1) to follow up on correspondence regarding BIKTARVY® (Lot CDGXKA) and (2) to seek cooperation with your investigation into BIKTARVY® (Lot CCXKVA). As an initial matter, Safe Chain is committed to fully cooperating with your investigation. We proactively take action to prevent the distribution and sale of counterfeit products, including working with Federal and Local authorities to enforce laws.

Regarding (1) BIKTARVY® (Lot CDGXKA), Safe Chain contacted your QC Complaints office on October 5, 2020 attempting to verify T3 information which was provided to you together with a photo of the product bottle. The T3 information indicated you sold 5 bottles of that lot number to Rochester Drug Co-op, Inc in Fairfield, NJ. The matter was assigned PR-200633. It is important to point out that Safe Chain proactively contacted Gilead requesting T3 information verification.

Via email on November 9, 2020, more than a full month later, your office made a determination that the product was illegitimate. Your email stated "The information contained in the pedigree/transaction history is inconsistent with our records." You then indicated you determined the product as illegitimate. As you know, once Gilead, the manufacturer, made that determination on the basis

of T3 information, the manufacturer has a duty to report this to the Food and Drug Administration (FDA) on Form 3911 within 24 hours of that determination. As a wholesaler, we immediately quarantined the product and awaited further results of your investigation and/or recall instructions from your office which were not forthcoming. We had additional bottles of this lot which we placed in quarantine and have not yet returned. Due to the cost of the medication, we were going to return to our vendor for other product (not this lot). While we understand the financial implications to Gilead that a product recall may trigger, FDA notification was your responsibility inasmuch as your investigation revealed the product was illegitimate and details of that investigation were only known to you and not shared with Safe Chain. At this juncture we are requesting you provide us with a copy of any documentation you submitted to the FDA for our records. Additionally, we respectfully request to know if Gilead has received any inquiries similar to PR-200633, detected any similar problems or reports involving your third-party manufacturers, or has conducted any recalls to the Wholesale or Retail Level of BIKTARVY® bearing Lot # CDGXKA.

- **Just wanted to add- the customer White Cross did not return product to our facility, they sent it directly to Gilead. This conflicts with the information you provided in the email chain of 11/25 where you stated there was no complaint and you were just seeking info about the Expiration date. Your email stated the PA lot.**

Regarding (2) BIKTARVY® (Lot CCXKVA), your November 23rd letter is the first time we are being contacted that there is an investigation into this Lot number. Your letter indicated you have identified the bottle in question contained foreign tablets instead of BIKTARVY ® and that Safe Chain Solutions, Inc. may be a possible source. Although you have not indicated that particular bottle of that particular lot came from Safe Chain, or another wholesaler, as a precautionary measure and with our full cooperation, we have quarantined the particular lot in question and are attaching our T3 information. Please advise us upon making a determination of the wholesaler involved. We would also ask for a copy of your correspondence with the FDA. Additionally, please provide any recall notification once you make that determination with FDA.

I am available to discuss this matter further should you require clarification. Please provide the requested information and response no later than December 11, 2020.

Respectfully,

**FRIER LEVITT, LLC**

**/s/ Martha M. Rumore**

Martha M. Rumore, PharmD, Esq

Attachment

cc: Safe Chain Solutions, Inc. (via email)