#### UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK

GILEAD SCIENCES, INC. and GILEAD	:	
SCIENCES IRELAND UC,	:	
	:	Case No.
Plaintiffs,	:	
	:	
V.	:	FILED EX PARTE AND UNDER SEAL
	:	PURSUANT TO 15 U.S.C. § 1116(d)
SAFE CHAIN SOLUTIONS, LLC; PATRICK	:	
BOYD; CHARLES BOYD; WORLDWIDE	:	
PHARMA SALES GROUP, INC. d/b/a	:	
PHARMASALES.COM; ADAM S. BROSIUS;	:	
BOULEVARD 9229 LLC; and ISHBAY	:	
SHUKUROV,	:	
	:	
Defendants.	:	

#### **DECLARATION OF SUSMITHA SUNKARA**

I, Susmitha Sunkara, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am Director, Quality, at Gilead Sciences, Inc. ("Gilead"). I submit this declaration in support of Gilead's and Gilead Sciences Ireland UC's motions for an *ex parte* seizure order, asset freeze order, expedited discovery order, temporary restraining order, and order to show cause for a preliminary injunction.

2. I am fully familiar with the facts discussed in this declaration.

#### **Credentials**

3. I have 20 years of experience in quality assurance and quality control, and I have worked in Gilead's quality assurance department since November 2015. I am responsible for Gilead's annual product quality reviews for all Gilead drug products and drug substances worldwide. I am responsible for product quality complaint management for Gilead's commercial and clinical drug products and critical issue management such as recalls. I develop and implement quality assurance programs and initiatives, such as establishing a centralized global complaint management program to track and investigate issues and complaints. I work closely with Gilead's manufacturing and packaging facilities. I also assist in Gilead's anti-counterfeiting and brand protection efforts, and over the years have examined hundreds of suspected counterfeit products.

#### **Background**

4. Gilead has received a number of complaints from patients and pharmacies concerning sealed bottles of BIKTARVY<sup>®</sup> and DESCOVY<sup>®</sup> that contained foreign tablets or objects rather than the indicated medication, which each pharmacy had purchased from Safe Chain Solutions LLC ("Safe Chain").

5. Under my supervision, Gilead's Quality department investigated these complaints to determine whether the bottles were genuine or counterfeit and investigated whether the foreign tablets could have been introduced during Gilead's manufacturing process. In addition, our investigation concluded that none of the foreign tablets could have been placed in the relevant bottles during Gilead's manufacturing process.

6. Gilead was not able in all instances to obtain a sample of the suspect bottles, but Gilead did obtain seven bottles for investigation and testing, and sufficient photographic evidence of an eighth bottle to allow a conclusion to be reached. In each of these eight investigations, our conclusion was that the BIKTARVY<sup>®</sup> or DESCOVY<sup>®</sup> was counterfeit. This conclusion was aided by laboratory analysis conducted by an outside facility, Triclinic Laboratories ("Triclinic").

#### **Quality Controls at Gilead's Manufacturing and Packaging Facilities**

7. Great care is taken at Gilead's manufacturing and packaging facilities to ensure the quality and consistency in all of Gilead's products.

8. At each manufacturing facility, there are multiple quality control procedures in place. For example, during the manufacturing process (tablet compression), checks of tablets are performed every 30 minutes. After compression, a sampling inspection is performed on the tablet cores. During the coating process, operators monitor the tablets for any visual defects, and samples are taken at the end of the coating process for a visual evaluation. There are cleaning procedures in place to prevent foreign material from coming into contact with the product being manufactured, and a complete clean is performed between different product manufacturing runs. To prepare the products for transportation to the packaging facility, the bulk drums are sealed with a security cable to prevent tampering with the product and to mitigate the risk of cross contamination. Manufacturing personnel wear uniforms and are not permitted to bring food, drink, or any medicinal products into the production area.

9. At each packaging facility, there are multiple quality control procedures in place. Upon receipt of the bulk containers, each container is inspected to ensure that it is sealed and unopened. A sampling of tablets is performed to detect defects, including identifying any contaminated or incorrect products. The packaging room is cleaned and inspected prior to the set-up of the lot. The production line includes a filler vision system, which is specifically calibrated to the specific shape and dimensions of the specific product being packaged. There is also a checkweigher to detect underfilled and overfilled bottles. The production line is covered between the filling station and the induction sealer, so there is no opportunity for the introduction

of foreign material into the unsealed bottles. Every 30 minutes, bottles off the packaging line are sampled to check for tablet damage, bottle fill, and seal integrity.

#### **Quality Controls in Gilead's Distribution Chain**

10. In the United States, to ensure quality and accountability across its distribution chain, Gilead sells its pharmaceutical products only to U.S. Gilead-authorized distributors. In the United States, there are only sixteen Gilead-authorized distributors for BIKTARVY® or DESCOVY®. Each of Gilead's authorized distributors works directly with Gilead to ensure supply chain transparency and compliance with the Drug Supply Chain Security Act (DSCSA) and all other applicable laws and regulations. Any pedigree document that shows an initial sale to any distributor other than a Gilead-authorized distributor must have been falsified. By purchasing from a Gilead-authorized distributor, a pharmacy can trust that they are receiving genuine Gilead products. Gilead cannot ensure the safety or efficacy of products purchased on the secondary market from companies that are not Gilead-authorized distributors.

11. Safe Chain is not and has never been a Gilead-authorized distributor.

12. None of the following companies, all of which are listed as selling counterfeit Gilead products to Safe Chain on falsified pedigree documents, is or has ever been a Gileadauthorized distributor: Gentek LLC, Rapids Tex Wholesales Corp., Mr. Unlimited LLC, Boulevard 9229 LLC, and Synergy Group Wholesalers LLCs.

13. In the United States, Gilead sells its HIV medicines to authorized distributors at the wholesale acquisition cost (WAC). WAC is Gilead's list price for the product to its authorized distributors.

14. Both BIKTARVY<sup>®</sup> and DESCOVY<sup>®</sup> must be dispensed to the patient in its original packaging, and the FDA-approved label for each states that the medication must be

dispensed only in its original container. Both products are shipped in bottles of 30 pills and include a silica gel desiccant and polyester fiber coil inside of the sealed bottle. Because of the required desiccant, among other reasons, these medications are not permitted to be repackaged by a distributor or pharmacy.

15. Gilead's bottles are heat-sealed with a tamper-evident foil seal. Because the foil is fused into the grooves on the bottle for the screw-on cap, it is extremely difficult to fully remove the original foil along the rim of the bottle.

#### **BIKTARVY®** Lot CDFYCA Containing SEROQUEL XR®

16. In February 2021, Gilead Quality Assurance was informed by a pharmacist at The Medicine Shoppe Pharmacy #1802 that a bottle of BIKTARVY<sup>®</sup> lot CDFYCA contained only SEROQUEL XR<sup>®</sup> 300 tablets ("CDFYCA Complaint Bottle"). The pharmacist reported that The Medicine Shoppe had reported the incident to Safe Chain in October 2020, but did not hear back from or receive any follow-up from Safe Chain. Gilead received the CDFYCA Complaint Bottle on February 25, 2021.

17. Safe Chain provided pedigree documentation to Gilead for the CDFYCA Complaint Bottle. The pedigree document states that Safe Chain received the CDFYCA Complaint Bottle from Gentek LLC, which in turn received the bottle from Drogueria Betances, a Gilead authorized distributor. The pedigree document is falsified. The address listed on the document for Gilead is incorrect. Gilead did not sell any bottles of BIKTARVY<sup>®</sup> lot CDFYCA to Drogueria Betances. Further, Drogueria Betances has confirmed to Gilead that Gentek LLC is not a customer and has never received products from Drogueria Betances. A copy of the pedigree document provided by Safe Chain is attached as **Exhibit 1**.

18. In a letter dated February 22, 2021, Safe Chain claimed that it had previously reported lot CDFYCA from the Medicine Shoppe Pharmacy #1802 to Gilead, and that Gilead did not respond to Safe Chain's report. That claim is inconsistent with Gilead's records. Gilead keeps careful records of all reports and complaints concerning suspect product, and it has no record of receiving any communications from Safe Chain concerning lot CDFYCA or any complaint from the Medicine Shoppe prior to Safe Chain's February 22, 2021 letter to Gilead. I understand that Gilead requested that Safe Chain substantiate its claim to have previously reported lot CDFYCA to Gilead, and that Safe Chain has not done so.

19. The CDFYCA Complaint Bottle was examined by a Gilead packaging engineer. The CDFYCA Complaint Bottle is missing the 2D matrix code from the base of the bottle that was present on the genuine retain bottle, indicating that the CDFYCA Complaint Bottle had been tampered with. The analysis from Triclinic indicated that physical remnants of two seals were observed on the CDFYCA Complaint Bottle. Chemical analysis confirmed that the second (top) seal was applied over the original (bottom) sealapplied by Gilead's packager, and the adhesive from the second seal does not match the adhesive found on the genuine retain bottle. This confirms that the bottle was opened and resealed after leaving Gilead's packaging facility. I therefore conclude that the CDFYCA Complaint Bottle is counterfeit.

20. It is not possible that the SEROQUEL XR<sup>®</sup> tablets were introduced at Gilead's manufacturing facility during the manufacture of BIKTARVY<sup>®</sup> lot CDFYCA. In addition to the quality control procedures discussed above, the facility that manufactured genuine BIKTARVY<sup>®</sup> lot CDFYCA does not manufacture SEROQUEL XR<sup>®</sup> 300, and the facility lacks the tooling set for the debossing present on those tablets. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

21. It is not possible that the SEROQUEL XR<sup>®</sup> tablets were introduced at Gilead's packaging facility during the packing of BIKTARVY<sup>®</sup> lot CDFYCA. In addition to the quality control procedures discussed above, the facility that bottled genuine BIKTARVY<sup>®</sup> lot CDFYCA does not package or receive SEROQUEL XR<sup>®</sup> 300, and the bottling line is dedicated to Gilead products. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

#### BIKTARVY® Lot CCZCBA Containing SEROQUEL XR®

22. In February 2021, Gilead Quality Assurance was informed by a pharmacist at Elm Drugs in New York that a patient reported receiving a sealed bottle of BIKTARVY<sup>®</sup> lot CCZCBA that contained only SEROQUEL XR<sup>®</sup> 300 tablets ("CCZCBA Complaint Bottle"). The pharmacist reported that Elm Drugs has never dispensed or stocked any medication that resembles the foreign tablet. Gilead received the CCZCBA Complaint Bottle on March 2, 2021.

23. According to the patient, he could neither speak nor walk after consuming a tablet from the CCZCBA Complaint Bottle.

24. The pharmacy provided pedigree documentation for the CCZCBA Complaint Bottle. The pedigree document states that Safe Chain received the CCZCBA Complaint Bottle from Gentek LLC, which in turn received the bottle from Gilead. The pedigree document is falsified. The pedigree document is missing an address for Gilead, and there is no "Date Purchased" or "Date Received" on the listed sale from Gilead to Gentek. Moreover, Gentek is not a Gilead-authorized distributor, and Gilead has never sold BIKTARVY<sup>®</sup> to Gentek. A copy of the pedigree document provided by Safe Chain is attached as **Exhibit 2**.

25. The CCZCBA Complaint Bottle was examined by a Gilead packaging engineer. Although the bottle appears to be authentic, there was physical evidence of two visible foil seal

layers around the rim of the bottle. In addition, the CCZCBA Complaint Bottle is missing the 2D matrix code from the base of the bottle that was present on the genuine retain bottle, indicating that the CCZCBA Complaint Bottle had been tampered with. The analysis from Triclinic confirmed physical remnants of two seals on the CCZCBA Complaint Bottle. Chemical analysis confirmed that the second (top) seal was applied over the original (bottom) seal applied by Gilead's packager, and the adhesive from the second seal does not match the adhesive found on the genuine retain bottle. This confirms that the bottle was opened and resealed after leaving Gilead's packaging facility. I therefore conclude that the CCZCBA Complaint Bottle is counterfeit.

26. It is not possible that the SEROQUEL XR<sup>®</sup> tablets were introduced at Gilead's manufacturing facility during the manufacture of BIKTARVY<sup>®</sup> lot CCZCBA. In addition to the quality control procedures discussed above, the facility that manufactured genuine BIKTARVY<sup>®</sup> lot CCZCBA does not manufacture SEROQUEL XR<sup>®</sup> 300, and the facility lacks the tooling set for the debossing present on those tablets. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

27. It is not possible that the SEROQUEL XR<sup>®</sup> tablets were introduced at Gilead's packaging facility during the packing of BIKTARVY<sup>®</sup> lot CCZCBA. In addition to the quality control procedures discussed above, the facility that bottled genuine BIKTARVY<sup>®</sup> lot CCZCBA does not package or receive SEROQUEL XR<sup>®</sup> 300, and the bottling line is dedicated to Gilead products. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

#### BIKTARVY<sup>®</sup> Lot CDGWZA Containing SEROQUEL XR<sup>®</sup>

28. In April 2021, Gilead Quality Assurance was informed by a patient in Bronx, New York about receiving a sealed bottle of BIKTARVY<sup>®</sup> lot CDGWZA that contained only SEROQUEL XR<sup>®</sup> 300 tablets ("CDGWZA Complaint Bottle"). The patient reported consuming one of the foreign tablets. According to the patient, the induction seal on the bottle was intact. Due to asserted privacy reasons, the patient refused to ship the CDGWZA Complaint Bottle to Gilead.

29. The dispensing pharmacy of the CDGWZA Complaint Bottle was identified as Legend Drugs 1 LLC in Bronx, New York. According to the pharmacist, the pharmacy inspects all bottles for intact induction seals prior to dispense.

30. The pharmacy provided an invoice that indicated that the CDGWZA Complaint Bottle was purchased from Safe Chain. Safe Chain provided a pedigree document indicating Safe Chain received the CDGWZA Complaint Bottle from Mr. Unlimited LLC, which received it from Rapids Tex Wholesale Corp., which in turn received it from AmerisourceBergen Corp. ("AmerisourceBergen"), a Gilead authorized distributor. The pedigree documentation for the CDGWZA Complaint Bottle is falsified. The address listed on the document for Gilead is incorrect. Further, although the pedigree document indicates that Gilead sold BIKTARVY<sup>®</sup> lot CDGWZA to AmerisourceBergen on January 19, 2021, Gilead's lot shipment reports confirmed that all BIKTARVY<sup>®</sup> lot CDGWZA was sold in July and August 2020. A copy of the pedigree document provided by Safe Chain is attached as **Exhibit 3**.

31. Although the CDGWZA Complaint Bottle was not shipped to Gilead, a Gilead packaging engineer reviewed photographs of the CDGWZA Complaint Bottle. Although the label appears to be authentic, one photograph showed what appear to be the polyester fiber coil

adhered to the bottle's seal. This is not consistent with Gilead packaging, as the polyester fiber coil in a genuine BIKTARVY<sup>®</sup> bottle would not be adhered to the bottle's seal. This is evidence of tampering and after-market sealing, which is consistent with the secondary seal found on the other counterfeit bottles. I therefore conclude that the CDGWZA Complaint Bottle is counterfeit.

32. It is not possible that the SEROQUEL XR<sup>®</sup> tablets were introduced at Gilead's manufacturing facility during the manufacture of BIKTARVY<sup>®</sup> lot CDGWZA. In addition to the quality control procedures discussed above, the facility that manufactured genuine BIKTARVY<sup>®</sup> lot CDGWZA does not manufacture SEROQUEL XR<sup>®</sup> 300, and the facility lacks the tooling set for the debossing present on those tablets. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

33. It is not possible that the SEROQUEL XR<sup>®</sup> tablets were introduced at Gilead's packaging facility during the packing of BIKTARVY<sup>®</sup> lot CDGWZA. In addition to the quality control procedures discussed above, the facility that bottled genuine BIKTARVY<sup>®</sup> lot CDGWZA does not package or receive SEROQUEL XR<sup>®</sup> 300, and the bottling line is dedicated to Gilead products. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

#### **BIKTARVY® Lot CCZCFA Containing STRIBILD®**

34. In February 2021, Safe Chain informed Gilead that a patient received a sealed bottle of BIKTARVY<sup>®</sup> lot CCZCFA from Medicine Shoppe Pharmacy #1802 in Silver Spring, Maryland that contained only STRIBILD<sup>®</sup> ("CCZCFA Complaint Bottle"). The pharmacy reported that it inspected the CCZCFA Complaint Bottle before dispensing to ensure that the seal was intact. Gilead received the CCZCFA Complaint Bottle on February 25, 2021. 35. Safe Chain provided pedigree documentation for the CCZCFA Complaint Bottle. The pedigree document states that Safe Chain received the CCZCFA Complaint Bottle from Gentek LLC, which in turn received the bottle from Drogueria Betances, a Gilead authorized distributor. The pedigree document is falsified. The address listed on the document for Gilead is incorrect. Gilead did not sell any bottles of BIKTARVY<sup>®</sup> lot CCZCFA to Drogueria Betances. Further, Drogueria Betances has confirmed to Gilead that Gentek LLC is not a customer and has never received products from Drogueria Betances. A copy of the pedigree document provided by Safe Chain is attached as **Exhibit 4**.

36. The CCZCFA Complaint Bottle was examined by a Gilead packaging engineer and the bottle appears to be authentic. However, the CCZCFA Complaint Bottle is missing the 2D matrix code from the base of the bottle that was present on the genuine retain bottle, indicating that the CCZCFA Complaint Bottle had been tampered with. In addition, the analysis from Triclinic indicated physical remnants of two adhesives on the CCZCFA Complaint Bottle. Chemical analysis confirmed that one of the adhesives does not match the adhesive found on the genuine retain bottle. This confirms that the bottle was opened and resealed after leaving Gilead's packaging facility. I therefore conclude that the CCZCFA Complaint Bottle is counterfeit.

37. It is not possible that the STRIBILD<sup>®</sup> tablets were introduced at Gilead's manufacturing facility during the manufacture of BIKTARVY<sup>®</sup> lot CCZCFA. In addition to the quality control procedures discussed above, the facility that manufactured genuine BIKTARVY<sup>®</sup> lot CCZCFA does not manufacture STRIBILD<sup>®</sup>, and the facility lacks the tooling set for the debossing present on those tablets. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

38. It is not possible that the STRIBILD<sup>®</sup> tablets were introduced at Gilead's packaging facility during the packing of BIKTARVY<sup>®</sup> lot CCZCFA. In addition to the quality control procedures discussed above, the facility that bottled genuine BIKTARVY<sup>®</sup> lot CCZCFA does not package or receive STRIBILD<sup>®</sup>. Further, the STRIBILD<sup>®</sup> tablets weigh substantially more than BIKTARVY<sup>®</sup> tablets, so a bottle containing thirty STRIBILD<sup>®</sup> tablets would have been rejected by the checkweigher during the packaging process. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

#### BIKTARVY<sup>®</sup> Lot CDSFFA Containing GENVOYA<sup>®</sup>

39. In March 2021, Safe Chain informed Gilead that a patient received a sealed bottle of BIKTARVY<sup>®</sup> lot CDSFFA from Columbia Heights Pharmacy in Washington, D.C. that contained only GENVOYA<sup>®</sup> ("CDSFFA Complaint Bottle"). Gilead Quality Assurance contacted the pharmacy and was informed by a pharmacist that the patient was dispensed the CDSFFA Complaint Bottle on March 17, 2021, and the patient shipped the bottle on March 18. The pharmacist shipped the bottle back to Safe Chain and Safe Chain shipped it to Gilead.

40. Safe Chain provided pedigree documentation for the CDSFFA Complaint Bottle. The pedigree document states that Safe Chain received the CDSFFA Complaint Bottle from Boulevard 9229 LLC, which received it from Amsterdam Wellness Pharma, which in turn received it from AmerisourceBergen, a Gilead authorized distributor. The pedigree document is falsified. The document is incomplete as it is missing the manufacturer information for Gilead. Further, BIKTARVY<sup>®</sup> lot CDSFFA was manufactured in December 2019, but the first sale on the pedigree document, from Gilead to AmerisourceBergen, is listed as occurring in August 2019. A copy of the pedigree document provided by Safe Chain is attached as **Exhibit 5**. 41. The CDSFFA Complaint Bottle was examined by a Gilead packaging engineer. Although the bottle appears to be authentic, there was physical evidence of tampering. The label was wrinkled and uneven, and it appeared that the label may have been moved. The analysis from Triclinic confirmed evidence of tampering, including observed wrinkling and damaged label edges. In addition, the adhesive under the label of the CDSFFA Complaint Bottle was compared to the adhesive used in a genuine retain sample, and the CDSFFA Complaint Bottle had additional peaks identified as high-density polyethylene (HDPE), which was not detected in the genuine retain bottle label adhesive. This supports the conclusion that the label has been tampered and is not original to the bottle. I therefore conclude that the CDSFFA Complaint Bottle Bottle is counterfeit.

42. It is not possible that the GENVOYA<sup>®</sup> tablets were introduced at Gilead's manufacturing facility during the manufacture of BIKTARVY<sup>®</sup> lot CDSFFA. In addition to the quality control procedures discussed above, the facility that manufactured genuine BIKTARVY<sup>®</sup> lot CDSFFA does not manufacture GENVOYA<sup>®</sup>, and the facility lacks the tooling set for the debossing present on those tablets. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

43. It is not possible that the GENVOYA<sup>®</sup> tablets were introduced at Gilead's packaging facility during the packing of BIKTARVY<sup>®</sup> lot CDSFFA. In addition to the quality control procedures discussed above, at the time it bottled genuine BIKTARVY<sup>®</sup> lot CDSFFA, the packaging facility did not have GENVOYA<sup>®</sup> at their facility. The packaging facility had packaged GENVOYA<sup>®</sup> approximately five months prior to BIKTARVY<sup>®</sup> lot CDSFFA . Further, the GENVOYA<sup>®</sup> tablets weigh substantially more than BIKTARVY<sup>®</sup> tablets, so a bottle containing thirty GENVOYA<sup>®</sup> tablets would have been rejected by the checkweigher during the

packaging process. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

#### **BIKTARVY® Lot 19BIC038A Containing NORVIR®**

44. In March 2021, Safe Chain informed Gilead that a patient received a sealed bottle of BIKTARVY<sup>®</sup> lot 19BIC038A from Columbia Heights Pharmacy in Washington, D.C. that contained only NORVIR<sup>®</sup> ("19BIC038A Complaint Bottle"). Gilead Quality Assurance contacted the pharmacy and was informed by a pharmacist that the patient was dispensed the 19BIC038A Complaint Bottle on March 25, 2021, consumed one tablet, and returned the bottle to the pharmacy the same day. The pharmacist shipped the bottle back to Safe Chain and Safe Chain shipped it to Gilead. The pharmacy does not stock NORVIR<sup>®</sup>, and the pharmacist confirmed that the seal integrity is verified prior to dispensing.

45. Safe Chain provided pedigree documentation for the 19BIC038A Complaint Bottle. The pedigree document states that Safe Chain received the 19BIC038A Complaint Bottle from Mr. Unlimited LLC, which received it from Rapids Tex Wholesales Corp., which received it from Independent Pharmacy Coop, which in turn received it from Gilead. The pedigree document is falsified. The address listed on the document for Gilead is incorrect. Further, Gilead has never sold BIKTARVY<sup>®</sup> to Independent Pharmacy Coop, which is not and has never been a Gilead authorized distributor. A copy of the pedigree document provided by Safe Chain is attached as **Exhibit 6**.

46. The 19BIC038A Complaint Bottle was examined by a Gilead packaging engineer. Although the bottle appears to be authentic, there was physical evidence of two visible foil seal layers around the rim of the bottle, with polyester fiber coil stuck to the seal. The analysis from Triclinic confirmed physical remnants of two seals on the 19BIC038A Complaint Bottle.

Chemical analysis confirmed that the second (top) seal was applied over the original (bottom) seal applied by Gilead's packager, and the adhesive from the second seal does not match the adhesive found on the genuine retain bottle. This confirms that the bottle was opened and resealed after leaving Gilead's packaging facility. I therefore conclude that the 19BIC038A Complaint Bottle is counterfeit.

47. It is not possible that the NORVIR<sup>®</sup> tablets were introduced at Gilead's manufacturing facility during the manufacture of BIKTARVY<sup>®</sup> lot 19BIC038A. In addition to the quality control procedures discussed above, the facility that manufactured genuine BIKTARVY<sup>®</sup> lot 19BIC038A does not manufacture NORVIR<sup>®</sup> or any tablets resembling it. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

48. It is not possible that the NORVIR<sup>®</sup> tablets were introduced at Gilead's packaging facility during the packing of BIKTARVY<sup>®</sup> lot 19BIC038A. In addition to the quality control procedures discussed above, the facility that bottled genuine BIKTARVY<sup>®</sup> lot 19BIC038A does not package or receive NORVIR<sup>®</sup>, and the bottling line is dedicated to Gilead products. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

#### BIKTARVY® Lot CCXKVA Containing Extra Strength Headache Relief

49. In August 2020, Gilead Quality Assurance was informed by a pharmacist at White Cross Pharmacy in Brawley, California that a patient reported receiving a sealed bottle of BIKTARVY<sup>®</sup> lot CCXKVA that contained only extra strength headache relief (containing acetaminophen, aspirin, and caffeine) ("CCXKVA Complaint Bottle"). According to the pharmacist, the bottle was delivered to the patient's home on July 31, 2020, and returned to the pharmacy two weeks later. The pharmacist shipped the bottle to Gilead. The pharmacist confirmed that the bottle was sealed before dispense, and that the pharmacy does not dispense the foreign tablets identified in the CCXKVA Complaint Bottle.

50. Safe Chain provided pedigree documentation for the CCXKVA Complaint Bottle. The pedigree document states that Safe Chain received the CCXKVA Complaint Bottle from Gentek LLC, which received it from Drogueria Betances, a Gilead authorized distributor. The pedigree document is falsified. Gilead did not sell any bottles of BIKTARVY<sup>®</sup> lot CCXKVA to Drogueria Betances. Further, Drogueria Betances has confirmed to Gilead that Gentek LLC is not a customer and has never received products from Drogueria Betances. A copy of the pedigree document provided by Safe Chain is attached as **Exhibit 7**.

51. The CCXKVA Complaint Bottle was examined by a Gilead packaging engineer. Although the bottle appears to be authentic, there was physical evidence of two visible foil seal layers around the rim of the bottle. In addition, the CCXKVA Complaint Bottle is missing the 2D matrix code from the base of the bottle that was present on the genuine retain bottle, indicating that the CCXKVA Complaint Bottle had been tampered with. The analysis from Triclinic confirmed physical remnants of two seals on the CCXKVA Complaint Bottle. Chemical analysis confirmed that the second (top) seal was applied over the original (bottom) seal applied by Gilead's packager, and the adhesive from the second seal does not match the adhesive found on the genuine retain bottle. This confirms that the bottle was opened and resealed after leaving Gilead's packaging facility. I therefore conclude that the CCXKVA Complaint Bottle is counterfeit.

52. It is not possible that the extra strength headache relief tablets were introduced at Gilead's manufacturing facility during the manufacture of BIKTARVY<sup>®</sup> lot CCXKVA. In

addition to the quality control procedures discussed above, the facility that manufactured genuine BIKTARVY<sup>®</sup> lot CCXKVA does not manufacture extra strength headache relief tablets, and the facility lacks the tooling set for the debossing present on those tablets. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

53. It is not possible that the extra strength headache relief tablets were introduced at Gilead's packaging facility during the packing of BIKTARVY<sup>®</sup> lot CCXKVA. In addition to the quality control procedures discussed above, the facility that bottled genuine BIKTARVY<sup>®</sup> lot CCXKVA does not package or receive extra strength headache relief tablets, and the bottling line is dedicated to Gilead products. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

#### **DESCOVY® Lot 019815 Containing VIREAD®**

54. In March 2021, Gilead Quality Assurance was informed by a patient that the patient received a sealed bottle of DESCOVY<sup>®</sup> lot 019815 that contained only VIREAD<sup>®</sup> tablets ("019815 Complaint Bottle"). The patient picked up the 019815 Complaint Bottle from Capitol Hill Pharmacy in Washington, D.C. on February 26, 2021. The patient stated that the induction seal was intact. The patient shipped the 019815 Complaint Bottle to Gilead.

55. The pharmacy provided pedigree documentation for the 019815 Complaint Bottle, which showed that it was provided by Safe Chain, which received it from Boulevard 9229 LLC, which received it from Amsterdam Wellness Pharmacy, which in turn received it from AmerisourceBergen, which is a Gilead authorized distributor. The pedigree document is falsified. The pedigree document states that Gilead sold the 019815 Complaint Bottle to AmerisourceBergen in September 2019. However, the first distribution of DESCOVY<sup>®</sup> lot 019815 was not until January 2020. A copy of the pedigree document provided by the pharmacy is attached as **Exhibit 8**.

56. The 019815 Complaint Bottle was examined by a Gilead packaging engineer. The bottle cap and label are consistent with Gilead specifications for DESCOVY<sup>®</sup>. However, the bottle itself was not. Rather, the bottle was manufactured by a company that manufactures bottles used for some Gilead drugs, such as VIREAD<sup>®</sup>, but not the bottles used for genuine DESCOVY<sup>®</sup> lot 019815. Further, the bottle contained less desiccant than a genuine DESCOVY<sup>®</sup> lot 019815 would include. This indicates that the bottle is not genuine DESCOVY<sup>®</sup> lot 019815 bottle. In addition, the 019815 Complaint Bottle is missing the 2D matrix code from the base of the bottle that was present on the genuine retain bottle. I therefore conclude that the 019815 Complaint Bottle is counterfeit.

57. It is not possible that the VIREAD<sup>®</sup> tablets were introduced at Gilead's manufacturing facility during the manufacture of DESCOVY<sup>®</sup> lot 019815. In addition to the quality control procedures discussed above, the facility that manufactured genuine DESCOVY<sup>®</sup> lot 019815 does not manufacture VIREAD<sup>®</sup>. Further, the VIREAD<sup>®</sup> tablets weigh substantially more than DESCOVY<sup>®</sup> tablets, so a bottle containing thirty VIREAD<sup>®</sup> tablets would have been rejected by the checkweigher on the packaging line. Moreover, there were no process deviations or abnormalities identified from the facility for this lot.

58. It is not possible that the VIREAD<sup>®</sup> tablets were introduced at Gilead's packaging facility during the packing of DESCOVY<sup>®</sup> lot 019815. In addition to the quality control procedures discussed above, the facility that bottled genuine DESCOVY<sup>®</sup> lot 019815 had not packaged VIREAD<sup>®</sup> for approximately ten months prior to DESCOVY<sup>®</sup> lot 019815, during

which time the facility conducted fifty-four major cleans. Moreover, there were no process

deviations or abnormalities identified from the facility for this lot.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: July \_\_\_\_, 2021 \_\_\_\_\_, California

Susmitha Sunkara

# Sunkara Declaration Ex. 1

					DSCSA TR	ACEA		PORT		AUTHORIZED BY: POSITION:	EDEL RE COMPLIANCE I	-
	G			ITEM NU	MBER: 2501	l	NDC # 61958-	-2501-1	BIKT	ARVY, TAB 50,	/200/25MG (30	D/BT)
	DATE:	10/26/2020		INVOICE:	2736		PO:	01210349		MFG : GILE	AD SCIENCE	
CO	NTACT BUYER:	ADAM BRO	SIUS	EMAIL:	ADAM@PHARMAS	ALES.COM	CONTACT	SELLER: EDEL RE	YES	EMAIL:	SALES@GENTE	KUSA.COM
ТҮРЕ	INVOICE/DATE	QTY		SELLER:	SH	IPPED FRC	DM:	SOLD TO	):		SHIPPED TO:	
ті	2736 10/27/20	156	2	GENTEK LLC 03-274-3527			FORD , CT 06902	SAFE CHAIN SOL 215-595-39		822 CHESAPEAK	E DRIVE ,CAMBRIDGE	,MD 21613
тн	85199 10/26/20			UERIA BETANCES 39-488-2018	LUIS MUNOZ M	,	. ,	GENTEK LL 203-274-35		45 CEDAR ST U	NIT 3 , STAMFORD ,	, CT 06902
тн	10/28/20 114369 10/21/20		GI	LEAD SCIENCE ANUFACTURER	EAD SCIENCE			203-274-3527 DROGUERIA BETANCES 939-488-2018			MARIN AVE,ESQ. EL AGUAS, PR 00725	TROCHE,
					(Le	OT NUME	BERS)					
	LOT	EXP DATE	QTY	LOT	EXP DATE	QTY	LOT	EXP DATE	QTY	LOT	EXP DATE	QTY
	CCVDCA	05/31/2021	1	CDFYHA	09/30/2022	12						
	CDFYFA	09/30/2022	8	CDMHCA	11/30/2022	2						
	CDGWYA	09/30/2022	4	CDFYCA	09/30/2022	4						
	(bla	ank)		CDGXFA	10/31/2022	4						
	CDMHDA	12/31/2022	8	CDGWZA	10/31/2022	4						
	CDMGXA	11/30/2022	7	CDGXCA	10/31/2022	1						
	CDFXZA	09/30/2022	5	CDMHFA	12/31/2022	4						
	CDGXGA	10/31/2022	4	CDGXBA	10/31/2022	3						
	CDMGTA	10/31/2022	8	022058	12/31/2022	1						
	6400501A	09/30/2022	1	CDMHBA	11/30/2022	2						
	CDFYBA	09/30/2022	2	6400503A	09/30/2022	2						
	CDMGZA	11/30/2022	11	CCZCCA	08/31/2022	1						
	CDSDZA	12/31/2022	10	CDMGWA	10/31/2022	3						
	CDGXDA	10/31/2022	2	CCZCFA	08/31/2022	2						
	022054	11/30/2022	7	6341502A	06/30/2022	1						
	CDGXKA	10/31/2022	4	Gra	nd Total	156						
	CDMGSA	10/31/2022	11									
	CDGXHA	10/31/2022	12									
	CDSDYA	11/30/2022	4									
	6341503A	06/30/2022	1							GRAN	D TOTAL	156

"TS: Seller has complied with each applicable subsection of FDCA Sec. 581 (27)(A)-(G).

For Questions regarding your DSCA report or to authenticate a subsequent transaction, please contact SALES@GENTEKUSA.COM .

# Sunkara Declaration Ex. 2

#### Case 1:21-cv-04106-AMD-RER Document 8-2 Filed 07/22/21 Page 2 of 3 PageID #: 775 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000016418

#### (TI) Transaction Information

Drug Name, Streng BIKTARVY 30C1 50/200/25 MG NDC: G1958-250	ř,	Container Size:	Reference Number: Document Type:	01134800 Invoice
Lot Number	Quantity	Unique Serial #	Reference Date:	10/09/20
CCZCBA	3			
CCZBYA	8			
CCZBZA	1			

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES Manufacturer's information:

SOLD TO:	SHIPPED TO:
Name: GENTEK LLC	Name: GENTEK LLC
Address: 45 CEDAR ST UNIT 3	Address: 45 CEDAR ST UNIT 3
STAMFORD CT 06902	STAMFORD CT 06902
Date Purchased & Ref :	Date Received & Ref :
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 09/30/20 PO#01209960	SHIPPED TO:Name:SAFE CHAIN SOLUTIONSAddress:822 CHESAPEAKE DRCAMBRIDGE MD 21613Date Received & Ref :10/02/20RC#014464
SOLD TO:	SHIPPED TO:
Name: ELM DRUGS	Name: ELM DRUGS
Address: 56 7TH AVENUE	Address: 56 7TH AVENUE
NEW YORK NY 10011	NEW YORK NY 10011
Date Purchased & Ref : 10/09/20 01S31505002	Date Received & Ref : 10/09/20 01S31505002
SOLD TO:	SHIPPED TO:
Name:	Name:
Address:	Address:
Date Purchased & Ref :	Date Received & Ref :
SOLD TO:	SHIPPED TO:
Name:	Name:
Address:	Address:
Date Purchased & Ref :	Date Received & Ref :

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

<sup>(</sup>B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

<sup>(</sup>C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

### Case 1:21-cv-04106-AMD-RER Document 8-2 Filed 07/22/21 Page 3 of 3 PageID #: 776 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000016418

#### (TI) Transaction Information

Drug Name, Strengt BIKTARVY 30CT, 50/200/25 MG NDC: G1958-2501-	-	Container Size:	Reference Number: Document Type:	01134800 Invoice	
Lot Number	Quantity	Unique Serial #	Reference Date:	10/09/20	
CCZBXA	1				
			]		

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES Manufacturer's information:

SHIPPED TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Received & Ref :
SHIPPED TO:Name:SAFE CHAIN SOLUTIONSAddress:822 CHESAPEAKE DRCAMBRIDGE MD 21613Date Received & Ref :10/02/20RC#014464
SHIPPED TO: Name: ELM DRUGS Address: 56 7TH AVENUE NEW YORK NY 10011 Date Received & Ref : 10/09/20 01S31505002
SHIPPED TO: Name: Address: Date Received & Ref :
SHIPPED TO: Name: Address: Date Received & Ref :

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

<sup>(</sup>B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

<sup>(</sup>C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

# Sunkara Declaration Ex. 3

### Case 1:21-cv-04106-AMD-RER Document 8-3 Filed 07/22/21 Page 2 of 4 PageID #: 778 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000021624

#### (TI) Transaction Information

BIKTARVY 30C 50/200/25 MG NDC: 61958-250			Reference Number: Document Type:	01I45133 Invoice
Lot Number	Quantity	Unique Serial #	Reference Date:	03/18/21
022058	1			
6341503A	1			
6400504A	1			

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 1800 WHEELER AVENUE LA VER	RNE,CA 91750
SOLD TO: Name: AMERISOURCEBERGEN DRUG CP Address: 5500 NEW HORIZONS BLVD. NORTH AMITYVILLE NY 11701-1156 Date Purchased & Ref : 01/19/21 20791843	SHIPPED TO:Name:AMERISOURCEBERGEN DRUG CPAddress:5500 NEW HORIZONS BLVD.NORTH AMITYVILLE NY 11701-1156Date Received & Ref :01/19/2120791843
SOLD TO: Name: RAPIDS TEX WHOLESALES CRP Address: 10333 HARWIN DR. STE 263 HOUSTON TX 77036 Date Purchased & Ref : 02/11/21 9773934	SHIPPED TO:Name:RAPIDS TEX WHOLESALES CRPAddress:10333 HARWIN DR. STE 263HOUSTON TX 77036Date Received & Ref :02/11/219773934
SOLD TO: Name: MR.UNLIMITED, LLC Address: ATTN:ACCOUNTS RECEIVABLE BRENHAM TX 77833 Date Purchased & Ref : 03/16/21 52801RTWSC	SHIPPED TO: Name: MR.UNLIMITED, LLC Address: ATTN:ACCOUNTS RECEIVABLE BRENHAM TX 77833 Date Received & Ref : 03/16/21 52801RTWSC
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 03/15/21 PO#01212294	SHIPPED TO:Name:SAFE CHAIN SOLUTIONS - UTAddress:1812 W SUNSET BLVDST. GEORGE UT 84770Date Received & Ref :03/18/21RC#017704
SOLD TO: Name: LEGEND DRUGS 1 LLC Address: 159 E GUNHILL ROAD BRONX NY 10467 Date Purchased & Ref : 03/18/21 01S40091004	SHIPPED TO:Name:LEGEND DRUGS 1 LLCAddress:159 E GUNHILL ROADBRONX NY 10467Date Received & Ref :03/18/2101S40091004

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

### Case 1:21-cv-04106-AMD-RER Document 8-3 Filed 07/22/21 Page 3 of 4 PageID #: 779 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000021624

#### (TI) Transaction Information

BIKTARVY 30C 50/200/25 MG NDC: 61958-250			Reference Number: Document Type:	01I45133 Invoice
Lot Number	Quantity	Unique Serial #	Reference Date:	03/18/21
CDGWZA	1			
CDGXGA	2			
CDMGSA	1			

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 1800 WHEELER AVENUE LA VER	RNE,CA 91750
SOLD TO: Name: AMERISOURCEBERGEN DRUG CP Address: 5500 NEW HORIZONS BLVD. NORTH AMITYVILLE NY 11701-1156 Date Purchased & Ref : 01/19/21 20791843	SHIPPED TO:Name:AMERISOURCEBERGEN DRUG CPAddress:5500 NEW HORIZONS BLVD.NORTH AMITYVILLE NY 11701-1156Date Received & Ref :01/19/2120791843
SOLD TO: Name: RAPIDS TEX WHOLESALES CRP Address: 10333 HARWIN DR. STE 263 HOUSTON TX 77036 Date Purchased & Ref : 02/11/21 9773934	SHIPPED TO:Name:RAPIDS TEX WHOLESALES CRPAddress:10333 HARWIN DR. STE 263HOUSTON TX 77036Date Received & Ref :02/11/219773934
SOLD TO: Name: MR.UNLIMITED, LLC Address: ATTN:ACCOUNTS RECEIVABLE BRENHAM TX 77833 Date Purchased & Ref : 03/16/21 52801RTWSC	SHIPPED TO: Name: MR.UNLIMITED, LLC Address: ATTN:ACCOUNTS RECEIVABLE BRENHAM TX 77833 Date Received & Ref : 03/16/21 52801RTWSC
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref: 03/15/21 PO#01212294	SHIPPED TO:Name:SAFE CHAIN SOLUTIONS - UTAddress:1812 W SUNSET BLVDST. GEORGE UT 84770Date Received & Ref :03/18/21RC#017704
SOLD TO: Name: LEGEND DRUGS 1 LLC Address: 159 E GUNHILL ROAD BRONX NY 10467 Date Purchased & Ref : 03/18/21 01S40091004	SHIPPED TO:Name:LEGEND DRUGS 1 LLCAddress:159 E GUNHILL ROAD BRONX NY 10467Date Received & Ref :03/18/2101S40091004

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

### Case 1:21-cv-04106-AMD-RER Document 8-3 Filed 07/22/21 Page 4 of 4 PageID #: 780 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000021624

#### (TI) Transaction Information

Drug Name, Strengtl BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-(	C C	Container Size:	Reference Number: Document Type:	01I45133 Invoice	
Lot Number	Quantity	Unique Serial #	Reference Date:	03/18/21	
CDMGWA	1				

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 1800 WHEELER AVENUE LA VER	RNE,CA 91750
SOLD TO: Name: AMERISOURCEBERGEN DRUG CP Address: 5500 NEW HORIZONS BLVD. NORTH AMITYVILLE NY 11701-1156 Date Purchased & Ref : 01/19/21 20791843	SHIPPED TO: Name: AMERISOURCEBERGEN DRUG CP Address: 5500 NEW HORIZONS BLVD. NORTH AMITYVILLE NY 11701-1156 Date Received & Ref : 01/19/21 20791843
SOLD TO: Name: RAPIDS TEX WHOLESALES CRP Address: 10333 HARWIN DR. STE 263 HOUSTON TX 77036 Date Purchased & Ref : 02/11/21 9773934	SHIPPED TO:Name:RAPIDS TEX WHOLESALES CRPAddress:10333 HARWIN DR. STE 263HOUSTON TX 77036Date Received & Ref :02/11/219773934
SOLD TO: Name: MR.UNLIMITED, LLC Address: ATTN:ACCOUNTS RECEIVABLE BRENHAM TX 77833 Date Purchased & Ref : 03/16/21 52801RTWSC	SHIPPED TO: Name: MR.UNLIMITED, LLC Address: ATTN:ACCOUNTS RECEIVABLE BRENHAM TX 77833 Date Received & Ref : 03/16/21 52801RTWSC
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref: 03/15/21 PO#01212294	SHIPPED TO: Name: SAFE CHAIN SOLUTIONS - UT Address: 1812 W SUNSET BLVD ST. GEORGE UT 84770 Date Received & Ref : 03/18/21 RC#017704
SOLD TO: Name: LEGEND DRUGS 1 LLC Address: 159 E GUNHILL ROAD BRONX NY 10467 Date Purchased & Ref : 03/18/21 01S40091004	SHIPPED TO:Name:LEGEND DRUGS 1 LLCAddress:159 E GUNHILL ROADBRONX NY 10467Date Received & Ref :03/18/2101S40091004

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

# Sunkara Declaration Ex. 4

### Case 1:21-cv-04106-AMD-RER Document 8-4 Filed 07/22/21 Page 2 of 7 PageID #: 782 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000019202

#### (TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01			Reference Number: Document Type:	01I40811 Invoice	
Lot Number	Quantity	Unique Serial #	Reference Date:	01/08/21	
CDSDYA	2				
CDMGSA	1				
CDGXKA	2				

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 1800 WHEELER AVENUE LA VERNE, CA 91750

SOLD TO:	SHIPPED TO:
Name: DROGUERIA BETANCES	Name: DROGUERIA BETANCES
Address: LUIS MUNOZ MARIN AVE	Address: LUIS MUNOZ MARIN AVE
CAGUAS PR 00725	CAGUAS PR 00725
Date Purchased & Ref : 10/05/20 85160	Date Received & Ref : 10/05/20 85160
SOLD TO:	SHIPPED TO:
Name: GENTEK LLC	Name: GENTEK LLC
Address: 45 CEDAR ST UNIT 3	Address: 45 CEDAR ST UNIT 3
STAMFORD CT 06902	STAMFORD CT 06902
Date Purchased & Ref : 10/06/20 2719	Date Received & Ref : 10/06/20 2719
SOLD TO:	SHIPPED TO:
Name: SAFE CHAIN SOLUTIONS, LLC	Name: SAFE CHAIN SOLUTIONS
Address: 822 CHESAPEAKE DR	Address: 822 CHESAPEAKE DR
CAMBRIDGE MD 21613	CAMBRIDGE MD 21613
Date Purchased & Ref : 01/07/21 PO#01211389	Date Received & Ref : 01/08/21 RC#016349
SOLD TO:	SHIPPED TO:
Name: MEDICINE SHOPPE #1802	Name: MEDICINE SHOPPE #1802
Address: 10313 GEORGIA AVENUE #101	Address: 10313 GEORGIA AVENUE #101
SILVER SPRING MD 20902	SILVER SPRING MD 20902
Date Purchased & Ref : 01/08/21 01S36758001	Date Received & Ref : 01/08/21 01S36758001
SOLD TO:	SHIPPED TO:
Name:	Name:
Address:	Address:
Date Purchased & Ref :	Date Received & Ref :
Address:	Address:

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

<sup>(</sup>B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

<sup>(</sup>C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

### Case 1:21-cv-04106-AMD-RER Document 8-4 Filed 07/22/21 Page 3 of 7 PageID #: 783 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000019202

#### (TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01			Reference Number: Document Type:	01I40811 Invoice	
Lot Number	Quantity	Unique Serial #	Reference Date:	01/08/21	
CDMGTA	1				
CDMHCA	2		1		
CDGXFA	1		]		

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 1800 WHEELER AVENUE LA VERNE, CA 91750

SOLD TO:	SHIPPED TO:
Name: DROGUERIA BETANCES	
Address: LUIS MUNOZ MARIN AVE	Nume.
	Address: LUIS MUNOZ MARIN AVE
CAGUAS PR 00725	CAGUAS PR 00725
Date Purchased & Ref : 10/05/20 85160	Date Received & Ref : 10/05/20 85160
SOLD TO:	SHIPPED TO:
Name: GENTEK LLC	Name: GENTEK LLC
Address: 45 CEDAR ST UNIT 3	Address: 45 CEDAR ST UNIT 3
STAMFORD CT 06902	STAMFORD CT 06902
Date Purchased & Ref : 10/06/20 2719	Date Received & Ref : 10/06/20 2719
SOLD TO:	SHIPPED TO:
Name: SAFE CHAIN SOLUTIONS, LLC	Name: SAFE CHAIN SOLUTIONS
Address: 822 CHESAPEAKE DR	Address: 822 CHESAPEAKE DR
CAMBRIDGE MD 21613	CAMBRIDGE MD 21613
Date Purchased & Ref : 01/07/21 PO#01211389	Date Received & Ref : 01/08/21 RC#016349
SOLD TO:	SHIPPED TO:
Name: MEDICINE SHOPPE #1802	Name: MEDICINE SHOPPE #1802
Address: 10313 GEORGIA AVENUE #101	Address: 10313 GEORGIA AVENUE #101
SILVER SPRING MD 20902	SILVER SPRING MD 20902
Date Purchased & Ref : 01/08/21 01S36758001	Date Received & Ref : 01/08/21 01S36758001
SOLD TO:	SHIPPED TO:
Name:	Name:
Address:	Address:
Date Purchased & Ref :	Date Received & Ref :

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

<sup>(</sup>B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

### Case 1:21-cv-04106-AMD-RER Document 8-4 Filed 07/22/21 Page 4 of 7 PageID #: 784 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000019202

#### (TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01			Reference Number: Document Type:	01I40811 Invoice	
Lot Number	Quantity	Unique Serial #	Reference Date:	01/08/21	
6400505A	3				
CDGXBA	1				
CCZCFA	1				

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 1800 WHEELER AVENUE LA VERNE, CA 91750

SOLD TO:	SHIPPED TO:
Name: DROGUERIA BETANCES	
Address: LUIS MUNOZ MARIN AVE	Nume.
	Address: LUIS MUNOZ MARIN AVE
CAGUAS PR 00725	CAGUAS PR 00725
Date Purchased & Ref : 10/05/20 85160	Date Received & Ref : 10/05/20 85160
SOLD TO:	SHIPPED TO:
Name: GENTEK LLC	Name: GENTEK LLC
Address: 45 CEDAR ST UNIT 3	Address: 45 CEDAR ST UNIT 3
STAMFORD CT 06902	STAMFORD CT 06902
Date Purchased & Ref : 10/06/20 2719	Date Received & Ref : 10/06/20 2719
SOLD TO:	SHIPPED TO:
Name: SAFE CHAIN SOLUTIONS, LLC	Name: SAFE CHAIN SOLUTIONS
Address: 822 CHESAPEAKE DR	Address: 822 CHESAPEAKE DR
CAMBRIDGE MD 21613	CAMBRIDGE MD 21613
Date Purchased & Ref : 01/07/21 PO#01211389	Date Received & Ref : 01/08/21 RC#016349
SOLD TO:	SHIPPED TO:
Name: MEDICINE SHOPPE #1802	Name: MEDICINE SHOPPE #1802
Address: 10313 GEORGIA AVENUE #101	Address: 10313 GEORGIA AVENUE #101
SILVER SPRING MD 20902	SILVER SPRING MD 20902
Date Purchased & Ref : 01/08/21 01S36758001	Date Received & Ref : 01/08/21 01S36758001
SOLD TO:	SHIPPED TO:
Name:	Name:
Address:	Address:
Date Purchased & Ref :	Date Received & Ref :

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

<sup>(</sup>B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

### Case 1:21-cv-04106-AMD-RER Document 8-4 Filed 07/22/21 Page 5 of 7 PageID #: 785 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000019202

#### (TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01			Reference Number: Document Type:	01I40811 Invoice
Lot Number	Quantity	Unique Serial #	Reference Date:	01/08/21
CDGXDA	2			
CDFYHA	1		1	
CDGWYA	2		]	

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 1800 WHEELER AVENUE LA VERNE, CA 91750

SOLD TO:	SHIPPED TO:
Name: DROGUERIA BETANCES	
Address: LUIS MUNOZ MARIN AVE	Nume.
	Address: LUIS MUNOZ MARIN AVE
CAGUAS PR 00725	CAGUAS PR 00725
Date Purchased & Ref : 10/05/20 85160	Date Received & Ref : 10/05/20 85160
SOLD TO:	SHIPPED TO:
Name: GENTEK LLC	Name: GENTEK LLC
Address: 45 CEDAR ST UNIT 3	Address: 45 CEDAR ST UNIT 3
STAMFORD CT 06902	STAMFORD CT 06902
Date Purchased & Ref : 10/06/20 2719	Date Received & Ref : 10/06/20 2719
SOLD TO:	SHIPPED TO:
Name: SAFE CHAIN SOLUTIONS, LLC	Name: SAFE CHAIN SOLUTIONS
Address: 822 CHESAPEAKE DR	Address: 822 CHESAPEAKE DR
CAMBRIDGE MD 21613	CAMBRIDGE MD 21613
Date Purchased & Ref : 01/07/21 PO#01211389	Date Received & Ref : 01/08/21 RC#016349
SOLD TO:	SHIPPED TO:
Name: MEDICINE SHOPPE #1802	Name: MEDICINE SHOPPE #1802
Address: 10313 GEORGIA AVENUE #101	Address: 10313 GEORGIA AVENUE #101
SILVER SPRING MD 20902	SILVER SPRING MD 20902
Date Purchased & Ref : 01/08/21 01S36758001	Date Received & Ref : 01/08/21 01S36758001
SOLD TO:	SHIPPED TO:
Name:	Name:
Address:	Address:
Date Purchased & Ref :	Date Received & Ref :

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

<sup>(</sup>B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

### Case 1:21-cv-04106-AMD-RER Document 8-4 Filed 07/22/21 Page 6 of 7 PageID #: 786 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000019202

#### (TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01			Reference Number: Document Type:	01I40811 Invoice	
Lot Number	Quantity	Unique Serial #	Reference Date:	01/08/21	
CDMGWA	1				
6400501A	2		1		
CDMHBA	1		]		

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 1800 WHEELER AVENUE LA VERNE, CA 91750

SHIPPED TO: Name: DROGUERIA BETANCES Address: LUIS MUNOZ MARIN AVE CAGUAS PR 00725
Date Received & Ref : 10/05/20 85160
SHIPPED TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Received & Ref : 10/06/20 2719
SHIPPED TO:Name:SAFE CHAIN SOLUTIONSAddress:822 CHESAPEAKE DRCAMBRIDGE MD 21613Date Received & Ref :01/08/21RC#016349
SHIPPED TO:Name:MEDICINE SHOPPE #1802Address:10313 GEORGIA AVENUE #101SILVER SPRING MD 20902Date Received & Ref :01/08/2101S36758001
SHIPPED TO: Name: Address: Date Received & Ref :

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

<sup>(</sup>B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

<sup>(</sup>C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

### Case 1:21-cv-04106-AMD-RER Document 8-4 Filed 07/22/21 Page 7 of 7 PageID #: 787 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000019202

#### (TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01			Reference Number: Document Type:	01I40811 Invoice	
Lot Number	Quantity	Unique Serial #	Reference Date:	01/08/21	
CDGWZA	1				
6400506A	1				

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 1800 WHEELER AVENUE LA VERNE, CA 91750

SOLD TO:	SHIPPED TO:
Name: DROGUERIA BETANCES	
Address: LUIS MUNOZ MARIN AVE	Nume.
	Address: LUIS MUNOZ MARIN AVE
CAGUAS PR 00725	CAGUAS PR 00725
Date Purchased & Ref : 10/05/20 85160	Date Received & Ref : 10/05/20 85160
SOLD TO:	SHIPPED TO:
Name: GENTEK LLC	Name: GENTEK LLC
Address: 45 CEDAR ST UNIT 3	Address: 45 CEDAR ST UNIT 3
STAMFORD CT 06902	STAMFORD CT 06902
Date Purchased & Ref : 10/06/20 2719	Date Received & Ref : 10/06/20 2719
SOLD TO:	SHIPPED TO:
Name: SAFE CHAIN SOLUTIONS, LLC	Name: SAFE CHAIN SOLUTIONS
Address: 822 CHESAPEAKE DR	Address: 822 CHESAPEAKE DR
CAMBRIDGE MD 21613	CAMBRIDGE MD 21613
Date Purchased & Ref : 01/07/21 PO#01211389	Date Received & Ref : 01/08/21 RC#016349
SOLD TO:	SHIPPED TO:
Name: MEDICINE SHOPPE #1802	Name: MEDICINE SHOPPE #1802
Address: 10313 GEORGIA AVENUE #101	Address: 10313 GEORGIA AVENUE #101
SILVER SPRING MD 20902	SILVER SPRING MD 20902
Date Purchased & Ref : 01/08/21 01S36758001	Date Received & Ref : 01/08/21 01S36758001
SOLD TO:	SHIPPED TO:
Name:	Name:
Address:	Address:
Date Purchased & Ref :	Date Received & Ref :

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

<sup>(</sup>B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

<sup>(</sup>C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

# Sunkara Declaration Ex. 5

### Case 1:21-cv-04106-AMD-RER Document 8-5 Filed 07/22/21 Page 2 of 4 PageID #: 789 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000021008

#### (TI) Transaction Information

•	gth, Dosage Form, T, 50; 200; 25 mg		ABLET in 1 BOTTLE, PLASTIC ( Reference Number:	
NDC: 61958-2501-01			Document Type:	Invoice
Lot Number	Quantity	Unique Serial #	Reference Date:	03/01/21
020731	2			
022053	1			
022055	1			

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES Manufacturer's information:

SOLD TO: Name: AMERISOURCEBERGEN DRUG CP Address: 5500 NEW HORIZONS BLVD. NORTH AMITYVILLE NY 11701-1156	SHIPPED TO: Name: AMERISOURCEBERGEN DRUG CP Address: 5500 NEW HORIZONS BLVD. NORTH AMITYVILLE NY 11701-1156
Date Purchased & Ref : 08/21/19 A141306	Date Received & Ref : 08/21/19 A141306
SOLD TO: Name: AMSTERDAM WELLNESS PHARMA Address: 2091 AMSTERDAM AVE NEW YORK NY 10032-8210 Date Purchased & Ref : 10/17/19 20191017	SHIPPED TO:Name:AMSTERDAM WELLNESS PHARMAAddress:2091 AMSTERDAM AVENEW YORK NY 10032-8210Date Received & Ref :10/17/1920191017
SOLD TO: Name: BOULEVARD 9229 LLC Address: 9229 QUEENS BLVD REGO PARK NY 11374 Date Purchased & Ref: 03/01/21 12014	SHIPPED TO:Name:BOULEVARD 9229 LLCAddress:9229 QUEENS BLVDREGO PARK NY 11374Date Received & Ref :03/01/2112014
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref: 03/01/21 PO#01212108	SHIPPED TO:Name:SAFE CHAIN SOLUTIONSAddress:822 CHESAPEAKE DRCAMBRIDGE MD 21613Date Received & Ref :03/01/21RC#017381
SOLD TO: Name: COLUMBIA HEIGHTS PHARMACY Address: 3316 14TH ST NW WASHINGTON DC 20010 Date Purchased & Ref : 03/01/21 01S39266004	SHIPPED TO:Name:COLUMBIA HEIGHTS PHARMACYAddress:3316 14TH STREET NWWASHINGTON DC 20010Date Received & Ref :03/01/2101S39266004

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

### Case 1:21-cv-04106-AMD-RER Document 8-5 Filed 07/22/21 Page 3 of 4 PageID #: 790 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000021008

#### (TI) Transaction Information

•	gth, Dosage Form, T, 50; 200; 25 mg		ABLET in 1 BOTTLE, PLASTIC ( Reference Number:	
NDC: 61958-2501-01			Document Type:	Invoice
Lot Number	Quantity	Unique Serial #	Reference Date:	03/01/21
022057	4			
CDMHDA	1			
CDSFCA	2			

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES Manufacturer's information:

SOLD TO: Name: AMERISOURCEBERGEN DRUG CP Address: 5500 NEW HORIZONS BLVD. NORTH AMITYVILLE NY 11701-1156 Date Purchased & Ref : 08/21/19 A141306	SHIPPED TO: Name: AMERISOURCEBERGEN DRUG CP Address: 5500 NEW HORIZONS BLVD. NORTH AMITYVILLE NY 11701-1156 Date Received & Ref : 08/21/19 A141306
SOLD TO: Name: AMSTERDAM WELLNESS PHARMA Address: 2091 AMSTERDAM AVE NEW YORK NY 10032-8210 Date Purchased & Ref : 10/17/19 20191017	SHIPPED TO:   Name: AMSTERDAM WELLNESS PHARMA   Address: 2091 AMSTERDAM AVE   NEW YORK NY 10032-8210   Date Received & Ref : 10/17/19
SOLD TO: Name: BOULEVARD 9229 LLC Address: 9229 QUEENS BLVD REGO PARK NY 11374 Date Purchased & Ref : 03/01/21 12014	SHIPPED TO:Name:BOULEVARD 9229 LLCAddress:9229 QUEENS BLVDREGO PARK NY 11374Date Received & Ref :03/01/2112014
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 03/01/21 PO#01212108	SHIPPED TO:Name:SAFE CHAIN SOLUTIONSAddress:822 CHESAPEAKE DRCAMBRIDGE MD 21613Date Received & Ref :03/01/21RC#017381
SOLD TO: Name: COLUMBIA HEIGHTS PHARMACY Address: 3316 14TH ST NW WASHINGTON DC 20010 Date Purchased & Ref : 03/01/21 01S39266004	SHIPPED TO:Name:COLUMBIA HEIGHTS PHARMACYAddress:3316 14TH STREET NWWASHINGTON DC 20010Date Received & Ref :03/01/2101S39266004

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

### Case 1:21-cv-04106-AMD-RER Document 8-5 Filed 07/22/21 Page 4 of 4 PageID #: 791 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000021008

#### (TI) Transaction Information

Drug Name, Stren BIKTARVY 30C	• •	Container Size: /1; mg/1; mg/1, TABLET, 30 TA	BLET in 1 BOTTLE, PLASTIC ( Reference Number:	·
NDC: 61958-2501-01			Document Type:	Invoice
Lot Number	Quantity	Unique Serial #	Reference Date:	03/01/21
CDSFDA	2			
CDSFFA	2			
CDSFKA	2			

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES Manufacturer's information:

SOLD TO: Name: AMERISOURCEBERGEN DRUG CP Address: 5500 NEW HORIZONS BLVD. NORTH AMITYVILLE NY 11701-1156	SHIPPED TO: Name: AMERISOURCEBERGEN DRUG CP Address: 5500 NEW HORIZONS BLVD. NORTH AMITYVILLE NY 11701-1156
Date Purchased & Ref : 08/21/19 A141306	Date Received & Ref : 08/21/19 A141306
SOLD TO: Name: AMSTERDAM WELLNESS PHARMA Address: 2091 AMSTERDAM AVE NEW YORK NY 10032-8210 Date Purchased & Ref : 10/17/19 20191017	SHIPPED TO:Name:AMSTERDAM WELLNESS PHARMAAddress:2091 AMSTERDAM AVENEW YORK NY 10032-8210Date Received & Ref :10/17/1920191017
SOLD TO: Name: BOULEVARD 9229 LLC Address: 9229 QUEENS BLVD REGO PARK NY 11374 Date Purchased & Ref: 03/01/21 12014	SHIPPED TO:Name:BOULEVARD 9229 LLCAddress:9229 QUEENS BLVDREGO PARK NY 11374Date Received & Ref :03/01/2112014
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref: 03/01/21 PO#01212108	SHIPPED TO:Name:SAFE CHAIN SOLUTIONSAddress:822 CHESAPEAKE DRCAMBRIDGE MD 21613Date Received & Ref :03/01/21RC#017381
SOLD TO: Name: COLUMBIA HEIGHTS PHARMACY Address: 3316 14TH ST NW WASHINGTON DC 20010 Date Purchased & Ref : 03/01/21 01S39266004	SHIPPED TO:Name:COLUMBIA HEIGHTS PHARMACYAddress:3316 14TH STREET NWWASHINGTON DC 20010Date Received & Ref :03/01/2101S39266004

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

# Sunkara Declaration Ex. 6

### Case 1:21-cv-04106-AMD-RER Document 8-6 Filed 07/22/21 Page 2 of 3 PageID #: 793 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000021679

#### (TI) Transaction Information

Drug Name, Strer BIKTARVY-TAB NDC: 61958-250		Container Size:	Reference Number: Document Type:	01I45319 Invoice
Lot Number	Quantity	Unique Serial #	Reference Date:	03/22/21
19BIC038A	4			
CCZCBA	5			
CCZBZA	6			

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 1800 WHEELER AVENUE LA VERNE, CA 91750

SOLD TO: Name: Independent Pharmacy Coop Address: 1550 Columbus Street Sun Prairie WI 53590 Date Purchased & Ref: 01/27/21 8283771	SHIPPED TO:Name:Independent Pharmacy CoopAddress:1550 Columbus StreetSun Prairie WI 53590Date Received & Ref :01/27/218283771
SOLD TO: Name: RAPIDS TEX WHOLESALES CRP Address: 10333 HARWIN DR. STE 263 HOUSTON TX 77036 Date Purchased & Ref : 02/19/21 4487622	SHIPPED TO:Name:RAPIDS TEX WHOLESALES CRPAddress:10333 HARWIN DR. STE 263HOUSTON TX 77036Date Received & Ref :02/19/214487622
SOLD TO: Name: MR.UNLIMITED, LLC Address: 105 E MAIN ST SUITE 200B BRENHAM TX 77833 Date Purchased & Ref : 03/16/21 52802RTWSC	SHIPPED TO:Name:MR.UNLIMITED, LLCAddress:105 E MAIN ST SUITE 200BBRENHAM TX 77833BRENHAM TX 77833Date Received & Ref :03/16/2152802RTWSC
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 03/15/21 PO#01212298	SHIPPED TO:Name:SAFE CHAIN SOLUTIONS - UTAddress:1812 W SUNSET BLVDST. GEORGE UT 84770Date Received & Ref :03/19/21RC#017725
SOLD TO: Name: COLUMBIA HEIGHTS PHARMACY Address: 3316 14TH ST NW WASHINGTON DC 20010 Date Purchased & Ref : 03/22/21 01S41109001	SHIPPED TO: Name: COLUMBIA HEIGHTS PHARMACY Address: 3316 14TH STREET NW WASHINGTON DC 20010 Date Received & Ref : 03/22/21 01S41109001

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

### Case 1:21-cv-04106-AMD-RER Document 8-6 Filed 07/22/21 Page 3 of 3 PageID #: 794 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000021679

#### (TI) Transaction Information

Drug Name, Streng BIKTARVY-TAB-3 NDC: 61958-2501	90CT,	Container Size:	Reference Number: Document Type:	01I45319 Invoice	
Lot Number	Quantity	Unique Serial #	Reference Date:	03/22/21	
CCZBXA	5				
<u>-</u>			•		

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 1800 WHEELER AVENUE LA VERNE, CA 91750

	·
SOLD TO: Name: Independent Pharmacy Coop Address: 1550 Columbus Street Sun Prairie WI 53590 Date Purchased & Ref : 01/27/21 8283771	SHIPPED TO:Name:Independent Pharmacy CoopAddress:1550 Columbus StreetSun Prairie WI 53590Sun Prairie WI 53590Date Received & Ref :01/27/218283771
SOLD TO: Name: RAPIDS TEX WHOLESALES CRP Address: 10333 HARWIN DR. STE 263 HOUSTON TX 77036 Date Purchased & Ref : 02/19/21 4487622	SHIPPED TO:Name:RAPIDS TEX WHOLESALES CRPAddress:10333 HARWIN DR. STE 263HOUSTON TX 77036Date Received & Ref :02/19/214487622
SOLD TO: Name: MR.UNLIMITED, LLC Address: 105 E MAIN ST SUITE 200B BRENHAM TX 77833 Date Purchased & Ref : 03/16/21 52802RTWSC	SHIPPED TO:Name:MR.UNLIMITED, LLCAddress:105 E MAIN ST SUITE 200BBRENHAM TX 77833Date Received & Ref :03/16/2152802RTWSC
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 03/15/21 PO#01212298	SHIPPED TO:Name:SAFE CHAIN SOLUTIONS - UTAddress:1812 W SUNSET BLVDST. GEORGE UT 84770Date Received & Ref :03/19/21RC#017725
SOLD TO: Name: COLUMBIA HEIGHTS PHARMACY Address: 3316 14TH ST NW WASHINGTON DC 20010 Date Purchased & Ref : 03/22/21 01S41109001	SHIPPED TO:Name:COLUMBIA HEIGHTS PHARMACYAddress:3316 14TH STREET NWWASHINGTON DC 20010Date Received & Ref :03/22/2101S41109001

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

# Sunkara Declaration Ex. 7

### Case 1:21-cv-04106-AMD-RER Document 8-7 Filed 07/22/21 Page 2 of 2 PageID #: 796 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000014606

#### (TI) Transaction Information

BIKTARVY 30C 50/200/25 MG NDC: 61958-250			Reference Number: Document Type:	01I29926 Invoice
Lot Number	Quantity	Unique Serial #	Reference Date:	07/29/20
CCXKNA	2			
ССХКРА	4			
CCXKVA	2			

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 333 LAKESIDE DRIVE FOSTER CITY, CA 94404

SOLD TO: Name: DROGUERIA BETANCES Address: LUIS MUNOZ MARIN AVE CAGUAS PR 00725	SHIPPED TO: Name: DROGUERIA BETANCES Address: LUIS MUNOZ MARIN AVE CAGUAS PR 00725
Date Purchased & Ref : 07/15/20 114172	Date Received & Ref : 07/15/20 114172
SOLD TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Purchased & Ref: 07/23/20 851011	SHIPPED TO:Name:GENTEK LLCAddress:45 CEDAR ST UNIT 3STAMFORD CT 06902Date Received & Ref :07/23/20851011
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref: 07/28/20 PO#01209048	SHIPPED TO:Name:SAFE CHAIN SOLUTIONSAddress:822 CHESAPEAKE DRCAMBRIDGE MD 21613Date Received & Ref :07/29/20RC#013308
SOLD TO: Name: WHITE CROSS PHARMACY - BRAWLEY Address: 1222 W 5TH ST SAN BERNARDINO CA 92411 Date Purchased & Ref: 07/29/20 01S27133003	SHIPPED TO:Name:WHITE CROSS PHARMACYAddress:602 MAIN STBRAWLEY CA 92227Date Received & Ref :07/29/2001S27133003
SOLD TO: Name: Address:	SHIPPED TO: Name: Address:
Date Purchased & Ref :	Date Received & Ref :

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and

<sup>(</sup>B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

<sup>(</sup>C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

# Sunkara Declaration Ex. 8

### Case 1:21-cv-04106-AMD-RER Document 8-8 Filed 07/22/21 Page 2 of 2 PageID #: 798 SAFE CHAIN SOLUTIONS, LLC

# Drug Supply Chain Security Act Document Doc# 0000020675

#### (TI) Transaction Information

			Reference Number:	01143801
NDC: 61958-2002-01			Document Type:	Invoice
Lot Number	Quantity	Unique Serial #	Reference Date:	02/25/21
019274	1			
019815	1			

#### (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC Manufacturer's information: 1800 WHEELER AVENUE LA VERNE, CA 91750

	-		
SOLD TO:	SHIPPED TO:		
Name: AMERISOURCEBERGEN DRUG CP	Name: AMERISOURCEBERGEN DRUG CP		
Address: 5500 NEW HORIZONS BLVD.	Address: 5500 NEW HORIZONS BLVD.		
NORTH AMITYVILLE NY 11701-1156	NORTH AMITYVILLE NY 11701-1156		
Date Purchased & Ref: 09/23/19 PO#A141582	Date Received & Ref : 09/23/19 PO#A141582		
SOLD TO:	SHIPPED TO:		
Name: AMSTERDAM WELLNESS PHARMA	Name: AMSTERDAM WELLNESS PHARMA		
Address: 2091 AMSTERDAM AVE	Address: 2091 AMSTERDAM AVE		
NEW YORK NY 10032-8210	NEW YORK NY 10032-8210		
Date Purchased & Ref : 10/23/19 PO#20191023	Date Received & Ref : 10/23/19 PO#20191023		
SOLD TO: Name: BOULEVARD 9229 LLC Address: 9229 QUEENS BLVD REGO PARK NY 11374	SHIPPED TO: Name: BOULEVARD 9229 LLC Address: 9229 QUEENS BLVD REGO PARK NY 11374		
Date Purchased & Ref : 12/08/19 PO#01262122	Date Received & Ref : 12/08/19 PO#01262122		
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref: 02/22/21 PO#01212034	SHIPPED TO:Name:SAFE CHAIN SOLUTIONSAddress:822 CHESAPEAKE DRCAMBRIDGE MD 21613Date Received & Ref :02/23/21RC#017225		
SOLD TO:	SHIPPED TO:		
Name: CAPITOL HILL PHARMACY	Name: CAPITOL HILL PHARMACY		
Address: 650 PENNSYLVANIA AVE SE WASHINGTON DC 20003	Address: 650 PENNSYLVANIA AVE SE WASHINGTON DC 20003		
Date Purchased & Ref : 02/25/21 01S39788001	Date Received & Ref : 02/25/21 01S39788001		

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

(A) is authorized as required under the Drug Supply Chain Security Act;

(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 582;

(F) did not knowingly provide false transaction information; and