

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA, Plaintiff, v. PHARMACARE, INC., d/b/a Farmacias Rey; CHINA DISTRICT PR LLC, d/b/a ChinaTown & More, ChinaTown & More Express, and Chinatown and More Mega Stores; QUALITY TRANSPORT & DISTRIBUTION LLC; and JUAN REYNOSO a/k/a Juan Amado Reynoso Cabrera, Defendants.	CIVIL NO. _____ COMPLAINT FOR PERMANENT INJUNCTIVE RELIEF
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COMPLAINT FOR PERMANENT
INJUNCTIVE RELIEF

Plaintiff, the United States of America, alleges:

INTRODUCTION

1. The United States of America brings this action to enjoin and restrain Pharmacare, Inc., doing business as Farmacias Rey (“Pharmacare”), China District PR LLC, doing business as ChinaTown & More, ChinaTown & More Express, and China Town and More Mega Stores (“China District”), Quality Transport & Distribution, LLC (“QTD”), and Juan Reynoso, also known as Juan Amado Reynoso Cabrera (collectively, “defendants”), from selling, offering for sale, manufacturing for sale, distributing in commerce, or importing into the United States, any

consumer product or other product or substance in violation of the Consumer Product Safety Act (“CPSA”), 15 U.S.C. §§ 2051-2089; the Federal Hazardous Substances Act (“FHSA”), 15 U.S.C. §§ 1261-1278; and regulations issued thereunder.

2. The United States pursues this action on behalf of the U.S. Consumer Product Safety Commission (“CPSC”), an independent federal regulatory agency that enforces the CPSA, the FHSA, and related regulations. One of the purposes of the CPSC is to protect the public against unreasonable risks of injury associated with consumer products.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action under 28 U.S.C. §§ 1331 and 1345.

4. This Court also has jurisdiction, under 15 U.S.C. § 2071(a), to restrain any violation of section 2068 of the CPSA, and, under 15 U.S.C. § 1267(a), to restrain any violation of the FHSA.

5. Venue in the District of Puerto Rico is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

6. Defendant Pharmacare is a corporation organized and existing under the laws of Puerto Rico, with its headquarters and warehouse located at Lote 7, Calle B, Parque Industrial Saint Just, Trujillo Alto, Puerto Rico. Pharmacare operates various retail locations in Puerto Rico under the name Farmacias Rey. Pharmacare was formed as a corporation on November 8, 2000.

7. Defendant China District is a limited liability company organized and existing under the laws of Puerto Rico, with its headquarters and warehouse located at Lote 7, Calle B, Parque Industrial Saint Just, Trujillo Alto, Puerto Rico. China District operates various retail locations in Puerto Rico under the names ChinaTown & More, ChinaTown & More Express, and China Town and More Mega Stores. China District was formed as a limited liability company on

March 20, 2018.

8. Defendant QTD is a limited liability organized and existing under the laws of Puerto Rico, with its headquarters located at Rd. 844 Num 462, Urb Tulipan, San Juan, Puerto Rico. QTD was formed as a limited liability company on February 16, 2021.

9. Defendant Juan Reynoso, a/k/a Juan Amado Reynoso Cabrera, is the president of Pharmacare, China District, and QTD. Reynoso is responsible for ensuring compliance by Pharmacare, China District, and QTD with the requirements of the CPSA, FHSA, and the regulations issued thereunder. At all times relevant to this action, Reynoso formulated, directed, controlled, and participated in the acts and practices of Pharmacare, China District, and QTD, including the acts and practices alleged herein.

10. Pharmacare and China District are manufacturers and retailers, as defined in 15 U.S.C. § 2052(a)(11) and (13), of consumer products, including children's toys and articles that are subject to the requirements of the CPSA, the FHSA, and the regulations issued thereunder. QTD is a manufacturer, as defined in 15 U.S.C. § 2052(a)(11), of consumer products. At all relevant times herein, Pharmacare and China District imported and sold various consumer products, including children's toys and articles, art materials, bicycle helmets, latex balloons, and small carpets or rugs through the defendants' headquarters, warehouses, and/or retail locations.

11. Since March 9, 2017, the CPSC has collected 32 violative samples of consumer products from Pharmacare's import shipments at the Port of San Juan, Puerto Rico, and Pharmacare's retail locations. The 32 violative samples contained 87 violations of federal law, including children's products and toys with illegal levels of total lead content and phthalates; children's bicycle helmets that failed to meet the safety standard for bicycle helmets; children's pacifiers that failed to meet the requirements for pacifier labeling; children's rattles that failed to

meet the safety requirements for rattles; latex balloons, and children's toys or games containing latex balloons, lacking required cautionary labeling; art materials that failed to meet the requirements for art materials; and children's toys and articles lacking the required certification based on third-party testing and lacking tracking labels (*see* Appendix A). The CPSC issued Pharmacare a total of 10 notices, titled "Notice of Non-Compliance" and "Notice of Violation" (collectively, "Notices"), between June 9, 2017, and March 12, 2020, notifying Pharmacare and Reynoso (collectively, "the Pharmacare defendants") of the violations.

12. Since July 9, 2018, the CPSC has collected 84 violative samples of consumer products from China District's import shipments at the Port of San Juan, Puerto Rico, and China District's retail locations. The 84 violative samples contained 209 violations of federal law, including children's products and toys with illegal levels of total lead content; art materials that failed to meet the requirements for art materials; small carpets or rugs that failed to meet the flammability standard and lacked the required cautionary labels; and children's toys and articles lacking the required certification based on third-party testing and lacking tracking labels (*see* Appendix B). The CPSC issued China District a total of 15 Notices between August 2, 2018, and March 17, 2021, notifying China District and Reynoso (collectively, "the China District defendants") of the violations.

13. On or about February 16, 2021, Reynoso formed QTD, a company intended to import consumer products for defendants Pharmacare and China District.

VIOLATIONS OF THE CPSA

14. The CPSA prohibits the sale, offer for sale, manufacture for sale, distribution in commerce, or importation into the United States of any consumer product, or other product or substance that is regulated under the CPSA or any other Act enforced by the CPSC, that is not in

conformity with an applicable consumer product safety rule under the CPSA, or any similar rule, regulation, standard, or ban under any other Act enforced by the CPSC. 15 U.S.C. § 2068(a)(1).

15. Under the CPSA, it is unlawful to fail to furnish a certificate required by the CPSA or any other Act enforced by the CPSC. 15 U.S.C. § 2068(a)(6).

16. Under the CPSA, it is unlawful for any person to fail to comply with the tracking labels requirement in 15 U.S.C. § 2063, or any rule or regulation under that section. 15 U.S.C. § 2068(a)(6).

17. The defendants' violations of the CPSA provisions set forth in paragraphs 14 through 16 above are specified in Counts 1 through 5 below.

Count 1

18. The United States re-alleges and incorporates by reference paragraphs 1 through 17 of this Complaint as though fully set forth herein.

19. Under the CPSA, it is unlawful for any person to manufacture for sale, offer for sale, distribute in commerce, or import into the United States any children's toys or child care articles containing concentrations of more than 0.1 percent of certain phthalate compounds, including di-(2-ethylhexyl) phthalate ("DEHP"), dibutyl phthalate, or benzyl butyl phthalate. 15 U.S.C. § 2057c(a).

20. Samples of products collected from Pharmacare's import shipments are "children's toys" or "child care articles" as defined in 15 U.S.C. § 2057c(g)(1)(B) and (C). Four children's toys and child care articles exceeded the phthalate concentration limit, because they contained more than 0.1 percent of DEHP. Accordingly, the toys and child care articles cannot be manufactured for sale, offered for sale, distributed in commerce, or imported into the United States under the CPSA. The CPSC sent Pharmacare Notices dated June 9, 2017, and September 19, 2017,

notifying the Pharmacare defendants of the violations and requesting corrective action.

21. On these four occasions, the Pharmacare defendants manufactured for sale, offered for sale, distributed in commerce, or imported into the United States children's toys or child care articles containing phthalates in excess of the statutory limit, thereby violating 15 U.S.C. § 2068(a)(1).

Count 2

22. The United States re-alleges and incorporates by reference paragraphs 1 through 21 of this Complaint as though fully set forth herein.

23. Under the CPSA, it is unlawful for any person to sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States any bicycle helmet that fails to meet the requirements of the Safety Standard for Bicycle Helmets, 16 C.F.R. part 1203. 15 U.S.C. § 2068(a)(1); 15 U.S.C. § 6004(d)(2).

24. Two bicycle helmets collected from Pharmacare's import shipments failed to meet the instructions, labeling, certification, and/or performance requirements of the Safety Standard for Bicycle Helmets, 16 C.F.R. part 1203. Accordingly, the bicycle helmets cannot be sold, offered for sale, manufactured for sale, distributed in commerce, or imported into the United States under the CPSA. The CPSC sent Pharmacare a Notice dated September 18, 2017, notifying the Pharmacare defendants of the violations and requesting corrective action.

25. On these two occasions, the Pharmacare defendants sold, offered for sale, manufactured for sale, distributed in commerce, or imported into the United States bicycle helmets that failed to meet the instructions, labeling, certification, and/or performance requirements of the Safety Standard for Bicycle Helmets, thereby violating 15 U.S.C. § 2068(a)(1).

Count 3

26. The United States re-alleges and incorporates by reference paragraphs 1 through 25 of this Complaint as though fully set forth herein.

27. Under the CPSA, it is unlawful for any person to sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States any product, fabric, or related material that fails to meet the requirements of the Flammable Fabrics Act, 15 U.S.C. § 1191 *et seq.*, and regulations issued thereunder. 15 U.S.C. §§ 2068(a)(1), 2079, 1192(a).

28. “Small carpets” and “small rugs,” as defined in 16 C.F.R. § 1631.1(c) and (d), must meet flammability standards under the Standard for the Surface Flammability of Small Carpets and Rugs (FF 2-70), 16 C.F.R. part 1631. A General Conformity Certification (“GCC”) must be issued for the product under 15 U.S.C. § 2063(a)(1), or, if the product does not meet the applicable flammability standards, the product must be permanently labeled, prior to its introduction into commerce, with “FLAMMABLE (FAILS U.S. DEPARTMENT OF COMMERCE STANDARD FF 2-70): SHOULD NOT BE USED NEAR SOURCES OF IGNITION.” 16 C.F.R. § 1631.5.

29. The CPSC collected seven samples of “small carpets” or “small rugs,” as defined in 16 C.F.R. § 1631.1(c) and (d), from China District’s import shipments and retail locations. The samples did not have GCCs available and were not permanently labeled as required by 16 C.F.R. § 1631.5. Accordingly, the small carpets or small rugs cannot be sold, offered for sale, manufactured for sale, distributed in commerce, or imported into the United States under the CPSA. The CPSC sent China District Notices dated October 25, 2018; August 26, 2019; and December 16, 2019, notifying the China District defendants of the violations and requesting corrective action.

30. On these seven occasions, the China District defendants sold, offered for sale,

manufactured for sale, distributed in commerce, or imported into the United States small carpets or rugs that failed to conform with the Standard for the Surface Flammability of Small Carpets and Rugs (FF 2-70), 16 C.F.R. § 1631.5, thereby violating 15 U.S.C. §§ 2068(a)(1) and 1192(a).

Count 4

31. The United States re-alleges and incorporates by reference paragraphs 1 through 30 of this Complaint as though fully set forth herein.

32. Under the CPSA, every manufacturer of a children's product that is subject to a children's product safety rule must submit samples of the product to a third-party conformity assessment body for testing. The manufacturer must then issue a certificate, based upon such testing, that such children's product complies with each applicable children's product safety rule. 15 U.S.C. § 2063(a)(2).

33. Samples of toys and articles imported by Pharmacare and China District and collected from Pharmacare's and China District's import shipments and retail locations are "children's products" as defined in 15 U.S.C. § 2052(a)(2) and are subject to a "children's product safety rule" as defined in 15 U.S.C. § 2063(f)(1).

34. Twenty-nine sampled items collected from Pharmacare's import shipments and retail locations were required to have a certificate based on third-party testing for an applicable children's product safety rule, but failed to have one. The CPSC sent Pharmacare 10 Notices dated June 9, 2017; September 18, 2017; September 19, 2017; April 2, 2018; August 2, 2018; June 6, 2019; June 19, 2019; June 26, 2019; January 16, 2020; and March 12, 2020, notifying the Pharmacare defendants that the 29 samples of children's products lacked a certificate based upon third-party testing as required under 15 U.S.C. § 2063(a)(2) and requesting corrective action.

35. On these 29 occasions, the Pharmacare defendants failed to furnish certificates

based upon third-party testing for children's products that are subject to a children's product safety rule, thereby violating 15 U.S.C. § 2068(a)(6).

36. Sixty-seven sampled items collected from China District's import shipments and retail locations were required to have a certificate based on third-party testing for an applicable children's product safety rule, but failed to have one. The CPSC sent China District 13 Notices dated August 2, 2018; September 13, 2018; May 6, 2019; June 3, 2019; June 17, 2019; June 26, 2019; July 29, 2019; August 8, 2019; September 10, 2019; October 9, 2019; November 25, 2019; December 16, 2019; and March 17, 2021, notifying the China District defendants that these children's products lacked a certificate based upon third-party testing as required under 15 U.S.C. § 2063(a)(2) and requesting corrective action.

37. On these 67 occasions, the China District defendants failed to furnish certificates based upon third-party testing for children's products that are subject to a children's product safety rule, thereby violating 15 U.S.C. § 2068(a)(6).

Count 5

38. The United States re-alleges and incorporates by reference paragraphs 1 through 37 of this Complaint as though fully set forth herein.

39. Under the CPSA, every manufacturer of a children's product shall place permanent, distinguishing marks ("tracking labels") on the product and its packaging, which will enable the manufacturer and ultimate purchaser of the product to ascertain the location and date of production of the product, along with cohort information. 15 U.S.C. § 2063(a)(5).

40. Samples of toys and articles imported by Pharmacare and China District and collected from Pharmacare's and China District's import shipments and retail locations are "children's products" as defined in 15 U.S.C. § 2052(a)(2).

41. Twenty-seven children's products collected from Pharmacare's import shipments and retail locations failed to have tracking labels. The CPSC sent Pharmacare nine Notices dated June 9, 2017; September 18, 2017; September 19, 2017; April 2, 2018; August 2, 2018; June 6, 2019; June 19, 2019; June 26, 2019; and January 16, 2020, notifying them that their children's products lacked tracking labels as required under 15 U.S.C. § 2063(a)(5) and requesting corrective action.

42. On these 27 occasions, the Pharmacare defendants failed to comply with the requirement to have tracking labels on children's products, thereby violating 15 U.S.C. § 2068(a)(6).

43. Sixty-seven children's products collected from China District's import shipments and retail locations failed to have tracking labels or had insufficient tracking labels. The CPSC sent China District 13 Notices dated August 2, 2018; September 13, 2018; May 6, 2019; June 3, 2019; June 17, 2019; June 26, 2019; July 29, 2019; August 8, 2019; September 10, 2019; October 9, 2019; November 25, 2019; December 16, 2019; and March 17, 2021, notifying them that their children's products lacked tracking labels as required under 15 U.S.C. § 2063(a)(5) and requesting corrective action.

44. On these 67 occasions, the China District defendants failed to comply with the requirement to have tracking labels on children's products, thereby violating 15 U.S.C. § 2068(a)(6).

**VIOLATIONS OF THE CPSA AND FHSA – MISBRANDED AND BANNED
HAZARDOUS SUBSTANCES**

45. The United States re-alleges and incorporates by reference paragraphs 1 through 44 of the Complaint as though fully set forth herein.

46. Under the FHSA, it is unlawful to introduce, cause the introduction, deliver, or

deliver for introduction into interstate commerce any misbranded hazardous substance or banned hazardous substance. 15 U.S.C. § 1263(a).

47. Under the FHSA, it is unlawful to receive or cause the receipt of in interstate commerce, deliver, or proffer delivery for pay or otherwise, any misbranded hazardous substance or banned hazardous substance. 15 U.S.C. § 1263(c).

48. Under the CPSA, it is unlawful for any person to “sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States any consumer product, or other product or substance that is regulated under the CPSA or any other Act enforced by the CPSC, that is not in conformity with an applicable consumer product safety rule under the CPSA, or any similar rule, regulation, standard, or ban under any other Act enforced by the CPSC. 15 U.S.C. § 2068(a)(1).

49. Under the CPSA, it is unlawful for any person to sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States any consumer product, or product or substance that is a banned hazardous substance within the meaning of 15 U.S.C. § 1261(q)(1). 15 U.S.C. § 2068(a)(2)(D).

50. The defendants’ violations of the CPSA and FHSA provisions set forth in paragraphs 46 through 49 above are specified in Counts 6 through 10 below.

Count 6

51. The United States re-alleges and incorporates by reference paragraphs 1 through 50 of this Complaint as though fully set forth herein.

52. Under the FHSA, any children’s product containing lead in excess of the statutory limit is a banned hazardous substance. 15 U.S.C. § 1278a(a)(1). Children’s products containing more than .001 percent, or 100 parts per million, lead are banned hazardous substances. 15 U.S.C.

§ 1278a(a)(2).

53. Samples of products collected from Pharmacare's and China District's import shipments and retail locations are "children's products" as defined in 15 U.S.C. § 2052(a)(2).

54. Seventeen children's products collected from Pharmacare's import shipments and retail locations contained lead content in excess of the statutory limit. Accordingly, the children's products are banned hazardous substances. The CPSC sent Pharmacare six Notices dated June 9, 2017; April 2, 2018; August 2, 2018; June 6, 2019; June 26, 2019; and January 16, 2020, notifying the Pharmacare defendants of the violations and requesting corrective action.

55. On these 17 occasions, the Pharmacare defendants introduced or delivered for introduction, and caused the introduction or delivery for introduction, into interstate commerce banned hazardous substances, that is children's products containing lead, or received in interstate commerce such products, and delivered or proffered delivery thereof for pay or otherwise, thereby violating 15 U.S.C. §§ 1263(a), (c), 2068(a)(1) and (2)(D).

56. Sixty-two children's products collected from China District's import shipments and retail locations contained lead content in excess of the statutory limit. Accordingly, the children's products are banned hazardous substances. The CPSC sent China District 10 Notices dated September 13, 2018; May 6, 2019; June 26, 2019; July 29, 2019; August 8, 2019; August 26, 2019; September 10, 2019; October 9, 2019; November 25, 2019; and December 16, 2019, notifying the China District defendants of the violations and requesting corrective action.

57. On these 62 occasions, the China District defendants introduced or delivered for introduction, and caused the introduction or delivery for introduction, into interstate commerce banned hazardous substances, that is children's products containing lead, or received in interstate commerce such products, and delivered or proffered delivery thereof for pay or otherwise, thereby

violating 15 U.S.C. §§ 1263(a), (c), 2068(a)(1) and (2)(D).

Count 7

58. The United States re-alleges and incorporates by reference paragraphs 1 through 57 of this Complaint as though fully set forth herein.

59. Under the FHSA, a “banned hazardous substance” includes any toy or other article intended for use by children that is a “hazardous substance.” 15 U.S.C. § 1261(q)(1)(A). A “hazardous substance” includes any toy or other article intended for use by children, which the CPSC by regulation determined in accordance with 15 U.S.C. § 1262(e) presents a mechanical hazard. 15 U.S.C. § 1261(f)(1)(D). By regulation, the CPSC determined that any pacifier introduced into interstate commerce that does not meet the requirements for pacifiers under 16 C.F.R. part 1511 presents a “mechanical hazard,” and is thereby a “banned hazardous substance.” 16 C.F.R. § 1500.18(a)(8).

60. A sample of children’s articles collected from Pharmacare’s import shipment contained pacifiers that are “children’s products” as defined under 15 U.S.C. § 2052(a)(2). The sample lacked the following required labeling statement for pacifiers: “Warning – Do Not Tie Pacifier Around Child’s Neck as it Presents a Strangulation Danger.” 16 C.F.R. § 1511.7(a). Accordingly, the pacifiers are banned hazardous substances. The CPSC sent Pharmacare a Notice dated September 19, 2017, notifying the Pharmacare defendants of the violation and requesting corrective action.

61. On this occasion, the Pharmacare defendants introduced or delivered for introduction, and caused the introduction or delivery for introduction, into interstate commerce banned hazardous substances, that is, a children’s product that failed to meet pacifier labeling requirements, or received in interstate commerce such products, and delivered or proffered

delivery thereof for pay or otherwise, thereby violating 15 U.S.C. §§ 1263(a), (c), 2068(a)(1) and (2)(D).

Count 8

62. The United States re-alleges and incorporates by reference paragraphs 1 through 61 of this Complaint as though fully set forth herein.

63. Under the FHSA, a “banned hazardous substance” includes any toy or other article intended for use by children that is a “hazardous substance.” 15 U.S.C. § 1261(q)(1)(A). A “hazardous substance” includes any toy or other article intended for use by children, which the CPSC by regulation determined in accordance with 15 U.S.C. § 1262(e) presents a mechanical hazard. 15 U.S.C. § 1261(f)(1)(D). By regulation, the CPSC determined that any rattle introduced into interstate commerce that does not meet the requirements for rattles under 16 C.F.R. part 1510 presents a “mechanical hazard,” and is thereby a “banned hazardous substance.” 16 C.F.R. § 1500.18(a)(15).

64. A “rattle” is defined as “an infant’s toy, intended to be hand held, usually containing pellets or other small objects and which produces sounds when shaken.” 16 C.F.R. § 1510.2

65. A sample of children’s articles collected from Pharmacare’s import shipment contained rattles that are “children’s products” as defined in 15 U.S.C. § 2052(a)(2) that did not meet the safety requirements for rattles under 16 C.F.R. part 1510. Accordingly, the rattles are banned hazardous substances. The CPSC sent Pharmacare a Notice dated September 19, 2017, notifying the Pharmacare defendants of the violation and requesting corrective action.

66. On this occasion, the Pharmacare defendants introduced or delivered for introduction, and caused the introduction or delivery for introduction, into interstate commerce banned hazardous substances, that is, a children’s product that failed to meet safety requirements

for rattles, or received in interstate commerce such products, and delivered or proffered delivery thereof for pay or otherwise, thereby violating 15 U.S.C. §§ 1263(a), (c), 2068(a)(1) and (2)(D).

Count 9

67. The United States re-alleges and incorporates by reference paragraphs 1 through 66 of this Complaint as though fully set forth herein.

68. Under the Labeling of Hazardous Art Materials Act (“LHAMA”), any art material which has the potential to produce chronic adverse health effects and does not meet the requirements of LHAMA is a misbranded hazardous substance. 15 U.S.C. §§ 1262(b), 1277(a) and (b).

69. LHAMA and regulations issued thereunder define a chronic adverse health effect as “a persistent toxic effect(s) that develops over time from a single, prolonged, or repeated exposure to a substance.” 16 C.F.R. § 1500.14(b)(8)(i)(B)(3).

70. LHAMA and regulations issued thereunder define an art material as “any raw or processed material, or manufactured product, marketed or represented by the producer or repackager as intended for and suitable for . . . artists or crafts people of any age who create, or recreate in a limited number, largely by hand, works which may or may not have a practical use, but in which aesthetic considerations are paramount.” 16 C.F.R. § 1500.14(b)(8)(i)(B)(1) and (2). A producer includes the person or entity that manufactures, processes, or imports an art material. 16 C.F.R. § 1500.14(b)(8)(i)(B)(7).

71. LHAMA requires that the importer of art materials submit the product formulations to a toxicologist to have the product assessed for its potential to cause adverse chronic health effects before the product is entered into commerce. 16 C.F.R. § 1500.14(b)(8)(i)(C). Prior to the product entering commerce, the importer must submit to CPSC staff the criteria used to determine

whether the art materials have the potential for producing chronic adverse health effects and a list of art materials that require hazard warning labels under LHAMA. 16 C.F.R. § 1500.14(b)(8)(ii)(C).

72. An art material must be accompanied by a statement of conformance to ASTM D-4236. 16 C.F.R. § 1500.14(b)(8)(i)(C)(7). ASTM D-4236 is a labeling standard for chronic health hazards in art materials.

73. Four samples of products collected from a Pharmacare retail location constituted “art materials” as defined in 16 C.F.R. § 1500.14(b)(8)(i)(B)(1) and (2), and have the potential to produce chronic adverse health effects, as defined in 16 C.F.R. § 1500.14(b)(8)(i)(B)(3). The samples lacked a statement of conformance to ASTM D-4236. Accordingly, the art materials are misbranded hazardous substances. The CPSC sent Pharmacare a Notice dated March 12, 2020, notifying the Pharmacare defendants of the violations and requesting corrective action.

74. On these four occasions, the Pharmacare defendants introduced or delivered for introduction, and caused the introduction or delivery for introduction, into interstate commerce misbranded hazardous substances, that is, art materials, or received in interstate commerce such products, and delivered or proffered delivery thereof for pay or otherwise, thereby violating 15 U.S.C. §§ 1263(a), (c), and 2068(a)(1).

75. Six samples collected from China District’s import shipments and retail locations were products constituting “art materials” as defined in 16 C.F.R. § 1500.14(b)(8)(i)(B)(1) and (2), and have the potential to produce chronic adverse health effects, as defined in 16 C.F.R. § 1500.14(b)(8)(i)(B)(3). The samples lacked a statement of conformance to ASTM D-4236 and/or China District failed to submit to CPSC staff the required criteria used for toxicological assessment of the art materials. Accordingly, the art materials are misbranded hazardous substances. The

CPSC sent China District three Notices dated August 2, 2018; August 26, 2019; and March 23, 2020, notifying the China District defendants of the violations and requesting corrective action.

76. On these six occasions, the China District defendants introduced or delivered for introduction, and caused the introduction or delivery for introduction, into interstate commerce misbranded hazardous substances, that is, art materials, or received in interstate commerce such products, and delivered or proffered delivery thereof for pay or otherwise, thereby violating 15 U.S.C. §§ 1263(a), (c), 2068(a)(1).

Count 10

77. The United States re-alleges and incorporates by reference paragraphs 1 through 76 of this Complaint as though fully set forth herein.

78. Under the FHSA and the regulations issued thereunder, any latex balloon, or toy or game containing a latex balloon, which lacks the required cautionary statement is a misbranded hazardous substance. 15 U.S.C. §§ 1278(e), 1261(p); 16 C.F.R. § 1500.19(b).

79. The CPSC collected two samples of toys from Pharmacare's import shipments that contained latex balloons as defined in 16 C.F.R. § 1500.19(a)(3). The samples lacked the following required cautionary statement for a latex balloon, or toy or game that contains a latex balloon: "CHOKING HAZARD - - Children under 8 yrs. can choke or suffocate on uninflated or broken balloons. Adult supervision required. Keep uninflated balloons from children. Discard broken balloons at once." 15 U.S.C. § 1278(b)(2)(A); 16 C.F.R. § 1500.19(b)(2). Accordingly, the samples containing latex balloons and lacking the required label are misbranded hazardous substances. 15 U.S.C. §§ 1261(p), 1278(e); 16 C.F.R. § 1500.19(b)(2). The CPSC sent Pharmacare a Notice dated June 9, 2017, notifying the Pharmacare defendants of the violations and requesting corrective action.

80. On these two occasions, the Pharmacare defendants introduced or delivered for introduction, and caused the introduction or delivery for introduction, into interstate commerce of misbranded hazardous substances, that is, latex balloons and toys or games containing a latex balloon lacking the required labeling, and received in interstate commerce such product and delivered or proffered delivery thereof for pay or otherwise, thereby violating 15 U.S.C. §§ 1263(a), (c) and 2068(a)(1).

RELIEF REQUESTED

81. Based on the defendants' past and present courses of conduct, defendant Reynoso's intention to use defendant QTD to import consumer products for Pharmacare and China District in the future, and defendant Reynoso's common ownership of Pharmacare, China District, and QTD, there is a substantial likelihood that, unless restrained by order of this Court pursuant to 15 U.S.C. §§ 2071(a) and 1267(a), defendants will continue to violate the CPSA, the FHSA, and other regulations issued thereunder.

WHEREFORE, the United States respectfully requests that this Court:

82. Pursuant to 15 U.S.C. § 2071(a), permanently restrain and enjoin the defendants and each and all of their directors, officers, agents, servants, brokers, employees, successors, assigns, attorneys, and all persons or entities in active concert or participation with any of them, from directly or indirectly selling, offering for sale, manufacturing for sale, distributing in commerce, or importing into the United States consumer products which do not conform to the consumer product safety statutes and regulations enforced by the CPSC, in violation of 15 U.S.C. § 2068(a)(1); selling, offering for sale, manufacturing for sale, distributing in commerce, or importing into the United States products that are banned hazardous substances within the meaning of 15 U.S.C. § 1261(q)(1) of the FHSA, in violation of 15 U.S.C. § 2068(a)(2)(D); and failing to

issue certificates and failing to include tracking labels required by 15 U.S.C. § 2063(a)(2), (3), and (5), in violation of 15 U.S.C. § 2068(a)(6).

83. Pursuant to 15 U.S.C. § 1267(a), permanently restrain and enjoin the defendants, and each and all of their directors, officers, agents, servants, brokers, employees, successors, assigns, attorneys, and all persons or entities in active concert or participation with any of them, from directly or indirectly introducing or causing the introduction and delivery for introduction into interstate commerce of misbranded hazardous substances or banned hazardous substances, and receiving or causing the receipt in interstate commerce of misbranded hazardous substances or banned hazardous substances and delivering or proffering delivery thereof for pay or otherwise, in violation of 15 U.S.C. §§ 1263(a), (c), 2068(a)(1), and (2)(D).

84. Pursuant to 15 U.S.C. §§ 2071(a) and 1267(a), award any further injunctive relief that is requested and agreed upon by the parties, as the Court deems necessary and proper.

Dated: September 15, 2021

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APPENDIX A

Pharmacare Defendants Summary of Violations

	<u>2017</u>	<u>2018</u>	<u>2019</u>	<u>2020</u>	<u>Total</u>
Lead Content	1	3	10	3	17
Phthalates	4	-	-	-	4
Art Materials (LHAMA)	-	-	-	4	4
Latex Balloon Labeling	2	-	-	-	2
Bicycle Helmet Standard	2	-	-	-	2
Rattles Requirements	1	-	-	-	1
Pacifier Requirements	1	-	-	-	1
Tracking Labels	9	3	12	3	27
Certificates	9	3	12	5	29
<u>Total # of Violations</u>	<u>29 violations</u>	<u>9 violations</u>	<u>34 violations</u>	<u>15 violations</u>	<u>87 violations</u>
Number of Notices	3	2	3	2	10
Number of Violative Samples	10	3	12	7	32

The year column reflects the calendar year that the Notice was issued.

APPENDIX B

China District Defendants Summary of Violations

	<u>2018</u>	<u>2019</u>	<u>2020</u>	<u>2021</u>	<u>Total</u>
Lead Content	2	60	-		62
FFA- Small rugs or carpets	3	4	-		7
Art Materials (LHAMA)	2	2	2		6
Tracking Labels	3	63	-	1	67
Certificates	3	63	-	1	67
<u>Total # of Violations</u>	<u>13 violations</u>	<u>192 violations</u>	<u>2 violations</u>	<u>2 violations</u>	<u>209 violations</u>
<u>Number of Notices</u>	3	11	(An amendment to a 2019 Notice)	1	15
<u>Number of Violative Samples</u>	7	74	2	1	84

The year column reflects the calendar year that the Notice was issued.