UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of BABY MATTERS, LLC Respondent.	)	CPSC DOCKET NO. 13-1 HON. WALTER J. BRUDZINSKI Administrative Law Judge

MEMORANDUM IN SUPPORT OF MOTION FOR LEAVE TO FILE AMENDED COMPLAINT

On December 4, 2012, Complaint Counsel issued a Complaint authorized by the U.S. Consumer Product Safety Commission (Commission). The Complaint seeks a determination that Respondent's infant recliners (the Subject Products) constitute a "substantial product hazard" within the meaning of Section 15 of the Consumer Product Safety Act (CPSA), as amended, 15 U.S.C. § 2064, and Section 15 of the Federal Hazardous Substances Act (FHSA), as amended, 15 U.S.C. § 1274. On December 26, 2012, Respondent filed an Answer.

Complaint Counsel requests that the Court grant leave to file the Amended Complaint, which, in keeping with Commission regulations, does not "unduly broaden the issues in the proceedings or cause undue delay." 16 C.F.R § 1025.13. The Commission's rules are "guided by principles stated and developed in case law interpreting the Federal Rules of Civil Procedure." 45 Fed. Reg. 29206, 29209 (May 1, 1980). Federal case law provides that, pursuant to Rule 15(a) of the Federal Rules of Civil Procedure, "leave sought should, as the rules require, be 'freely given.'" *Foman v. Davis*, 371 U.S. 178, 182 (1962).

The proposed amendments would not unduly broaden the issues in this proceeding. The amendments do not add any additional counts, but instead supplement the allegations alleged in the Complaint. For example, the proposed amendments add details about incidents in which the Subject Products were used as directed on the floor with harnesses secured around the infants, but nonetheless resulted in infants being placed at risk with their heads or bodies hanging over the side of the Subject Product. *See* Exh. A at ¶¶ 3, 95. The proposed amendments also supplement and clarify allegations concerning the alleged substantial product hazards posed by the Subject Products, in particular the risks associated with Respondent's Nap Nanny Chill products. *See id.* at ¶¶ 25-26, 54-55, 86, 93, 139-142. As such, the amendments do not unduly broaden the issues in this proceeding.

The proposed amendments also would not cause undue delay. Complaint Counsel has filed this motion seeking the proposed amendments less than two months after the filing of the Complaint and before any discovery has been served on Respondent. In light of this short timeframe, the proposed amendments are timely. *See, e.g., Williams v. Citigroup Inc.*, 659 F.3d 208, 214 (2nd Cir. 2011) (holding that motion seeking leave to amend even after judgment did not constitute "undue delay" in light of "the liberal spirit of Rule 15"), citing *Foman*, 317 U.S. at 182.

Conclusion

For the foregoing reasons, Complaint Counsel respectfully requests that the Court grant leave to file the Amended Complaint.

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In the Matter of BABY MATTERS, LLC Respondent.	)	CPSC DOCKET NO. 13-1 HON. WALTER J. BRUDZINSKI Administrative Law Judge

ORDER

This matter having come before the Court on Complaint Counsel's Motion for Leave to File an Amended Complaint, and upon consideration of the Motion and any other pleadings of record, it is by this Court, this ____ day of _____ 2013,

ORDERED that leave to file the Amended Complaint attached to Complaint Counsel's Motion is GRANTED, and it is further

ORDERED that the Amended Complaint attached to Complaint Counsel's Motion is accepted for filing.

_____

Walter J. Brudzinski

Administrative Law Judge

EXHIBIT A

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of BABY MATTERS, LLC, Respondent.	)	CPSC DOCKET NO. 13-1

AMENDED COMPLAINT

Nature of Proceedings

1. This is an administrative enforcement proceeding pursuant to Section 15 of the Consumer Product Safety Act ("CPSA"), as amended, 15 U.S.C. § 2064, and Section 15 of the Federal Hazardous Substances Act ("FHSA"), as amended, 15 U.S.C. § 1274, for public notification and remedial action to protect children from the substantial risks of injury and death presented by infant recliners known as the Nap Nanny® and the Nap Nanny® Chill™ (collectively, the "Subject Products"), imported, distributed and sold by Baby Matters, LLC ("Respondent").

2. Upon information and belief, since 2009, there have been at least five infants who died while using the Subject Products.

3. Upon information and belief, there have been at least 92 incident reports of infants hanging over the side or nearly falling out of the Subject Products, including some infants who were restrained in the Subject Product's harness.

4. This proceeding is governed by the Rules of Practice for Adjudicative Proceedings before the Consumer Product Safety Commission (the "Commission"), 16 C.F.R. Part 1025.

Jurisdiction

5. This proceeding is instituted pursuant to the authority contained in Sections 15(c), (d) and (f) of the CPSA, 15 U.S.C §§ 2064 (c), (d) and (f), and Sections 15(c), (d) and (e) of the FHSA, 15 U.S.C. §§ 1274(c), (d) and (e).

Parties

6. Complaint Counsel is the staff of the Division of Compliance within the Office of the General Counsel of the Commission ("Complaint Counsel"). The Commission is an independent federal regulatory agency established pursuant to Section 4 of the CPSA, 15 U.S.C. § 2053.

7. Baby Matters, LLC is a Pennsylvania limited liability company with its principal place of business located at 531 Winston Way, Berwyn, Pennsylvania, 19312.

8. Baby Matters, LLC does business as Nap Nanny, LLC, which is a registered Pennsylvania fictitious name owned by Baby Matters, LLC.

9. From January 2009 until November 2012, Respondent was an importer, distributor, and retailer of the Subject Products, as those terms are defined in CPSA Sections 3(a)(5), (7), (8), (11) and (13) of the CPSA, 15 U.S.C. §§ 2052(a)(5), (7), (8), (11) and (13).

10. As an importer, from January 2009 until November 2012, Respondent was a "manufacturer" as that term is defined in CPSA Section 3(a)(11), 15 U.S.C. § 2052(a)(11).

The Consumer Product

11. From January 2009 until November 2012, Respondent imported and distributed the Subject Products in U.S. commerce and offered them for sale to consumers for their personal use in or around a permanent or temporary household or residence, in recreation or otherwise.

12. The Subject Products are sold under the brand names Nap Nanny® ("Nap Nanny"), and The Nap Nanny® Chill™" (the "Chill").

13. Upon information and belief, three models of the Nap Nanny have been introduced in U.S. commerce.

14. Upon information and belief, one model of the Nap Nanny ("Generation One") was sold between January 2009 and August 2009.

15. Upon information and belief, the Generation One consists of a shaped foam seat base covered by a removable fabric shell, and is equipped with a three-point harness.

16. Upon information and belief, the harness on each Generation One Product is attached to the fabric cover only and is not secured to the foam base underneath.

17. Upon information and belief, a second model of the Nap Nanny ("Generation Two") was sold between August 2009 and as late as April 2012.

18. Upon information and belief, the Generation Two consists of a shaped foam seat base covered by a removable fabric shell and is equipped with a three-point harness.

19. Upon information and belief, the contour of the foam seat base of the Generation Two is identical to that of the Generation One.

20. Upon information and belief, the harness system in the Generation Two is sewn to the fabric cover but also can be secured to two "D"-shaped rings embedded in the foam base by means of Velcro™ tabs.

21. Upon information and belief, a third model of the Nap Nanny, the Chill, has been sold since January 2011.

22. Upon information and belief, the Chill consists of a shaped foam seat base covered by a removable fabric shell and is equipped with a three-point harness.

23. Upon information and belief, the contour of the Chill model's foam base has been modified from those of the Generation One and Generation Two versions of the Subject Products.

24. Upon information and belief, the contour of the Chill forms a more narrow space around the infant's hip area and provides a higher side wall on either side of the infant than do either the Generation One or Generation Two models of the Subject Products.

25. Upon information and belief, the harness in the Chill is not permanently attached to the foam base. As stated in the Chill User Guide, the "[h]arness may be removed completely for washing."

26. Upon information and belief, the Chill harness straps attach to three plastic buckles that are not secured to the base. Instead, the buckles are sewn into a small, removable crotch pad made of the same fabric as the subject product cover.

27. Upon information and belief, the foam core components of the Subject Products were manufactured by G&T Industries, of Reading, Pennsylvania.

28. Upon information and belief, the fabric covers of the Generation One and a portion of fabric covers of the Generation Two were manufactured by Ricochet Manufacturing, of Philadelphia, Pennsylvania.

29. Upon information and belief, the fabric covers for a portion of the Generation Two are manufactured by Jiaxing Jiayi Garment Co. Ltd., of Jiazing, Zhejiang, in China.

30. Upon information and belief, the fabric covers for the Chill are manufactured by Jiaxing Jiayi Garment Co. Ltd., of Jiazing, Zhejiang, in China.

31. Upon information and belief, Respondent imports these fabric covers into the United States.

32. Upon information and belief, the Subject Products have been, and continue to be, sold for a retail price of approximately $130.

33. Upon information and belief, approximately 5,000 units of the Generation One and 50,000 units of the Generation Two have been sold to consumers in the United States.

34. Upon information and belief, approximately 110,000 units of the Chill have been sold to consumers in the United States.

35. Upon information and belief, Respondent advised the public on its website in November 2012 that Respondent has "closed [its] doors," and directed consumers to Respondent's retail partners that continued to sell the Chill.

36. Upon information and belief, subsequently, on or about November 23, 2012, Respondent removed the message that it had "closed [its] doors" and replaced it with

links to the Chill's User Guide and registration. Respondent retained the message directing consumers to Respondent's retail partners that continued to sell the Chill.

COUNT 1

The Subject Products are Substantial Product Hazards Under Section 15(a)(2) of the CPSA, 15 U.S.C. § 2064(a)(2), Because They Contain Product Defects That Create a Substantial Risk of Injury to the Public

The Subject Products Contain a Design Defect

37. Paragraphs 1 through 36 are hereby realleged and incorporated by reference as though fully set forth herein.

38. A product may contain a defect even if a product is manufactured in exact accordance with its design and specifications, if the design presents a risk of injury to the public. 16 C.F.R. § 1115.4.

39. Upon information and belief, because the restraint system in the Generation One is designed such that the harness straps are secured only to the fabric cover and cannot be attached to the foam seat base, the fabric cover can move freely over the seat base so that there is no means of anchoring the harness to any fixed point.

40. Upon information and belief, this defective design allows the infant to have significant movement within the Generation One even when the harness is used.

41. Upon information and belief, the harness straps of the Generation One slide easily through the buckles when the infant user moves, preventing a secure, snug fit around the infant's waist.

42. Upon information and belief, this defective design allows freedom of movement such that the infant is able to maneuver over the side walls of the Generation One and

into other compromised positions. This hazardous scenario exists even while the harness is in use.

43. Upon information and belief, the restraint system in the Generation Two is designed such that the two harness straps that encircle the infant's waist are sewn to the fabric cover but also could be secured, via Velcro™ tabs, to two "D"-shaped rings embedded in the foam seat base. The third point of the harness is sewn to the fabric cover between the infant user's legs with no means of attaching it to a fixed point on the foam seat base, causing the harness straps to slide easily through the buckles and prevent a secure, snug fit around the infant's waist.

44. Upon information and belief, when the harness is not attached to the "D"-shaped rings, the Generation Two harness moves freely with the fabric cover.

45. Upon information and belief, some of the fabric covers of the Generation Two completely cover the foam base and are secured by a zipper. Other covers of the Generation Two, however, cover most of the seat and are secured with elastic over the foam.

46. Upon information and belief, this defective design allows an infant to fall or hang over the side of a Generation Two even while the harness is in use, which can result in injury or death.

47. Upon information and belief, parents and caregivers who remove the fabric cover of the Generation Two are directed in Respondent's instructions that failure to secure the harness around the "D" shaped rings can allow the infant to turn and contact the floor.

48. Upon information and belief, the Velcro™ tabs in the Generation Two loosen as the infant user moves in the seat.

49. Upon information and belief, over time, due to the nature of Velcro™, the tabs gradually detach with ease, thereby rendering the restraint system ineffective, posing a risk of injury and death to the infant.

50. Upon information and belief, parents or other caregivers using a Generation Two are not likely to immediately know that the Velcro™ tabs have detached from the "D"-shaped ring.

51. Upon information and belief, parents or other caregivers, may be unaware of the importance of ensuring that the Velcro™ tabs are secured around the "D"-shaped rings after replacing the cover and before every use.

52. Upon information and belief, because the harness straps in the Chill are looped though the base and then inserted into three point buckles on the removable crotch pad, this design makes it difficult for caregivers to adjust the waist straps.

53. Upon information and belief, because it is difficult to adjust the waist straps in the Chill, parents and other caregivers are less likely to use the harness.

54. Upon information and belief, because both the Chill harness straps and buckles are not securely attached to the base, they can be removed or can be lost. If either or both the harness straps or buckles are removed from the base, the Chill restraint system no longer functions and an infant can no longer be secured in the Chill.

55. Upon information and belief, because the Chill buckles are sewn into a small, removable crotch pad, both the pad and buckles must be removed from the Chill when

the pad needs to be machine washed according to instructions in the Chill User Guide. When the crotch pad and attached buckles have been removed from the Chill for washing, the restraint system no longer functions and a child cannot be restrained in the Chill.

56. Upon information and belief, due to the ineffectiveness of the Generation One and Two harness, parents and other caregivers are unlikely to use the harness on those products.

57. Upon information and belief, due to the difficulty of use of the Chill harness and foreseeable frequent need to remove the Chill crotch pad and attached buckles for washing, parents and other caregivers are unlikely to use the harness on those products.

58. Upon information and belief, even if the harness is used, the harness may fail to prevent the infant user from moving into a compromised position if it is not adequately tightened around the infant.

59. These defective designs pose a risk of injury and death to infant users.

The Subject Products Are Defective Because the Risk of Injury Occurs as a Result of their Operation or Use

60. A design defect may also be present if the risk of injury occurs as a result of the operation or use of the product. 16 C.F.R. § 1115.4.

61. Upon information and belief, the Subject Products have been advertised and marketed by Respondent as devices that promote a full night's sleep for infants.

62. Upon information and belief, Respondent has advertised the Generation Two product as suitable for babies with "reflux, gas, colic, ear infections, and colds & stuffiness."

63. Upon information and belief, the risk of injury occurs as a result of the use of the Subject Products by parents and caregivers who, contrary to the on-product warnings, are likely to use the product, regardless of the version, in cribs and other traditional sleep environments in order to ensure the child's safety during a full night's sleep.

64. Upon information and belief, the risk of injury occurs as a result of the foreseeable use and/or misuse of the Subject Products by parents and caregivers.

65. Upon information and belief, infants who are not adequately restrained in the Subject Products may move into compromised positions on the side or inside the seat well of the recliner, which can result in injury or death.

66. Upon information and belief, when a Subject Product is used in a crib, an infant may be able to maneuver its head over the side of the Subject Product and become entrapped between the Subject Product and a bumper pad of a crib or the side of a crib, which can result in injury or death.

67. The Subject Products contain a design defect because they fail to operate as intended and present a substantial risk of injury to the public.

The Subject Products Are Defective Because
Their Instructions and Warnings Are Inadequate

68. A defect can occur in a product's contents, construction, finish, packaging, warnings and/or instructions. 16 C.F.R. §1115.4.

69. A defect can occur when reasonably foreseeable consumer use or misuse, based in part on the lack of adequate instructions and safety warnings, could result in injury, even where there are no reports of injury. 16 C.F.R. §1115.4.

70. Upon information and belief, from approximately January 2009 through July 2010, all of the Generation One and Generation Two models had a warning label that read as follows: "Safety guidelines to prevent injury or death: FALL HAZARD: ALWAYS use on the floor. This product should not be used inside a crib. NEVER place product on countertops, tables, steps or other elevated surfaces. SUFFOCATION HAZARD: NEVER use on soft or uneven surface (sofa, bed cushion), as seat may tip over and cause suffocation. NEVER use with blankets, towels, pillows, or other soft objects while child is in seat. Intended for infants 8 pounds or 3.6 kilograms and above. NEVER leave child in the seat when straps are loose or undone. Adjust the straps provided so they fit snugly around the infant. NEVER move or carry unit while child is in seat. Not intended for carrying a baby."

71. Upon information and belief, this warning was printed in extremely small (approximately 6-point) font on the underside of the product, which would be placed on the floor or other surface and thus not visible to consumers during use.

72. Upon information and belief, some versions of the Generation Two Nap Nanny only contain a warning on a tag that is sewn inside the subject product and thus is not visible to consumers.

73. Upon information and belief, on or about April 17, 2010, a six-month-old girl died when she suffocated while using a Generation Two model of the Subject Products. Not secured in the harness, the infant was found with her face pressed between the Nap Nanny and the crib bumper. The medical examiner ruled the cause of death as probable positional asphyxia.

74. Upon information and belief, on or about July 9, 2010, a four-month-old girl died when she suffocated between a Generation Two Nap Nanny and the bumper in her crib. Although the harness had been secured around the infant, it failed to adequately restrain her in the seat. She was found by her mother in the Nap Nanny, with the harness secured but with her head tilted back and her neck hyperextended. Her face was pressed against the bumper pad of her crib. The medical examiner ruled the cause of death as position/compression asphyxia.

75. On July 26, 2010, the Commission and the Respondent issued a joint press release announcing a recall of the Generation One and the Generation Two models of the Subject Products: *Baby Matters Recalls Nap Nanny® Recliners Due to Entrapment, Suffocation and Fall Hazards; One Infant Death Reported.*

76. The April 17, 2010, infant death was not known to the Commission at the time of this recall. The July 9, 2010, infant death was known to the Commission at the time of this recall.

77. Upon information and belief, on or about July 26, 2010, Respondent executed a corrective action plan in cooperation with the U.S. Consumer Product Safety Commission. As part of this corrective action plan, Respondent modified the warnings, instructions, and labeling on the Generation Two products that were in Respondent's inventory at the time and on the Subject Products imported, sold, and distributed thereafter by Respondent.

78. Upon information and belief, as part of the corrective action, Respondent relocated the warning label from the underside of the Generation Two model to the front

of the Generation Two model, increased the font size of the warning, and changed the text of the warning label to read as follows: "ALWAYS use on floor. NEVER use in crib. ALWAYS secure buckles on harness. NEVER use with infant under 8 pounds (3.6 kilograms). When infant can sit up, do not use for sleep. Suffocation hazards: - Do not place inside crib, other contained areas, or on the floor next to other vertical surfaces (e.g., walls, dresser). An infant who leans over side can become entrapped between the product and another object. – Never use on soft surfaces (e.g., bed, sofa, cushion) where product can tip over and cause suffocation in soft surfaces. – Do not add blankets, towels, or other soft objects that can cover face. Fall hazards: - Never use on counter tops, tables or other elevated surfaces from which infant can fall. – Never carry product with infant in it. – ALWAYS secure infant snugly in harness or infant may turn sideways and fall. Strangulation hazards: - Head/neck can get caught in loosely fastened seatbelt if infant tries to get out of product. – Head/neck can get caught in a fastened seatbelt not in use if active infant tries to climb in and out of product unassisted."

79. Upon information and belief, the change in warning did not address the Subject Products that had already been purchased by consumers or that remained in retailers' inventory.

80. Upon information and belief, for products already purchased by consumers or those that remained in retailers' inventory, Respondent directed retailers with Generation Two products to place a sticker on the plastic bag covering the product.

81. Upon information and belief, the sticker directed users to a website, www.napnanny.com/recall, which contained the revised warnings and instructions that were part of the recall and corrective action plan.

82. Upon information and belief, Respondent has disabled the web page formerly located at www.napnanny.com/recall and instead now redirects visitors to the website's home page.

83. Upon information and belief, despite the requirement in the corrective action plan that Respondent direct retailers with Generation Two products to place on the bag covering the product a sticker directing consumers to a website where they could access revised warnings and instructions, Generation Two products continued to be sold without stickers required by the corrective action plan.

84. Upon information and belief, at the time of the recall, Respondent knew of the July 9, 2010 fatality, one injury, and 21 other incidents resulting from the failure of the harness systems on the Generation One and the Generation Two to properly secure the infant.

85. Upon information and belief, since the Chill was first introduced into commerce in January 2011, the warning label read as follows: "To avoid serious injury or death, read and follow the warnings and instructions provided below: ALWAYS use on floor. NEVER use in crib. ALWAYS secure buckles on harness. NEVER use with clothing or blankets that interfere with the use of the harness. Harness must always be snug against your child. NEVER use with infant under 8 pounds (3.6 kilograms). When infant can sit up, do not use for sleep. For infants who cannot sit up, use for sleep, feeding and play

time. ALWAYS secure infant snugly in harness or infant may turn sideways and fall. Suffocation hazards - Do not place inside crib, other contained areas, or on the floor next to other vertical surfaces (e.g., walls, dresser). An infant who leans over side can become entrapped between the product and another object. - Never use on soft surface (e.g., bed, sofa, cushion) where product can tip over and cause suffocation in soft surfaces. - Do not add blankets, towels, or other soft objects that can cover face. Fall hazards - Never use on counter tops, tables, or other elevated surfaces from which infant can fall. - Never carry product with infant in it. - ALWAYS secure infant snugly in harness or infant may turn sideways and fall. Strangulation hazards - Head/neck can get caught in loosely fastened seatbelt if infant tries to get out of product. - Head/neck can get caught in a fastened seatbelt not in use if active infant tries to climb in and out of product unassisted."

86. Upon information and belief, although some Chill units contain the warning label in a visible position near the head or foot of the infant, other Chill units contain a warning label near the bottom edge of the unit in a position that is difficult for users to see, particularly when the product is used on the floor.

87. Upon information and belief, subsequent to the July 2010 recall, and despite enhanced warnings and revised instructions on the Subject Products, parents and caregivers continue to use the Subject Products inside of cribs and other sleeping environments, contrary to the warnings on the Subject Products.

88. Upon information and belief, subsequent to the July 2010 recall, and despite enhanced warnings and revised instructions on the Subject Products, parents and

caregivers continue to use the Subject Products without using the harness or ensuring that the harness is firmly secured around the infant.

89. Upon information and belief, since the July 2010 recall, at least three additional fatalities of infants using the Subject Products have been reported.

90. Upon information and belief, on November 21, 2011, a four month old boy died when his face became entrapped against the Generation Two Nap Nanny and the bumper in his crib. He was found with his head tilted back and his neck hyperextended, and with his face up against the bumper pad. The infant was not harnessed in the Nap Nanny. The medical examiner ruled the cause of death as Sudden Unexplained Infant Death.

91. Upon information and belief, the Subject Product involved in the November 2011 fatality was a Generation Two model of the Nap Nanny that was already on a retailer's shelves at the time of the recall. Thus, the Subject Product would not have had the revised warnings and would have only had a sticker on the plastic bag advising consumers to contact www.napnanny.recall.com.

92. Upon information and belief, a four-month-old boy died on April 12, 2012, when his face became entrapped against the foam side wall of the seat of a Generation Two Nap Nanny. The Subject Product was being used on the floor when the incident occurred. The child was not harnessed into the Subject Product at the time of the death. The medical examiner ruled the cause of death as positional asphyxia.

93. Upon information and belief, on April 23, 2012, a seven-month-old boy was placed in a Chill in a crib by his mother at approximately 4:00 am. About two hours later, he was found dead between the Chill and the bumper in his crib. The Chill cover

and crotch pad with attached buckles had been removed for washing as directed by the washing instructions in the User Guide. The medical examiner ruled the cause of death as Sudden Unexplained Infant Death, but stated that accidental asphyxia could not be excluded as a cause of death.

94. Upon information and belief, subsequent to the July 2010 recall, over 70 additional incidents have been reported of children nearly falling out of the Subject Products, totaling at least 92 such incidents since the Subject Products were first sold.

95. Upon information and belief, the reported incidents include those in which the product was used on the floor with the harnesses secured around the infant, including:

a. A parent in New York reported that her three to four-month-old infant, who was harnessed into the Subject Product which was located on the floor, was found hanging over the side of the Subject Product and on a separate occasion was able to slide out of the Subject Product onto the floor.

b. A parent reported that their 10-week-old boy, who was harnessed into the Subject Product which was located on the floor, had fallen over the side of the Subject Product and was hanging upside down out of the Subject Product.

c. A parent in Arizona reported that her four-month-old girl, who was harnessed into the Subject Product which was located on the floor, was found partially falling out of the Subject Product.

d. A parent reported that their four-month-old boy, who was harnessed into the Subject Product which was located on the floor, was found with his head hanging off the side of the Subject Product which had flipped over on top of him.

e. A parent reported that their five-month-old boy, who was harnessed into the Subject Product which was located on the floor, had his head fall out of the Subject Product onto the floor even though the harness was tightly secured and kept his lower body still in the product.

f. A parent in Pennsylvania reported that her four-month-old boy, who was harnessed into the Subject Product which was located on the floor, was found hanging off the side of the Subject Product.

g. A parent reported that their four-month-old nephew, who was harnessed into the Subject Product which was located on the floor, rolled off the side of the product and hit his head face down on the floor.

h. A parent in Wisconsin reported that her two-month-old son, who was harnessed into the Subject Product which was located on the floor, was found hanging over the side of the Subject Product.

i. A parent reported that their infant daughter, who was harnessed into the Subject Product which was located on the floor, was able to get her head over the side of the product.

j. A parent in Texas reported that her four-month-old girl, who was harnessed into the Subject Product which was located on the floor, was found hanging upside down on the side of the Subject Product.

k. A parent reported that her four-month-old son, who was harnessed into the Subject Product which was located on the floor, was able to go over the side of the product and had the product flip over on top of the infant.

l. A parent reported that her three-month-old son, who was harnessed into the Subject Product which was located on the floor, was found with his head hanging off the side of the product.

m. A parent reported that her three-week-old infant, who was harnessed into the Subject Product which was located on the floor, was found over the side of the product with its feet entangled in the secured harness.

n. A parent reported that her five-month-old daughter, who was harnessed into the Subject Product which was located on the floor, was found hanging over the side of the Subject Product.

o. A parent in Oregon reported that her five-month-old daughter, who was buckled into the Subject Product which was located on the floor, was found hanging over the side of the product with her foot caught in the harness.

96. The warnings and instructions on the Subject Products are inadequate and defective because they do not and cannot effectively communicate to parents and

caregivers the hazard associated with use of the Subject Products inside cribs and other sleep enclosures.

97. The warnings and instructions on the Subject Products are inadequate and defective because they do not and cannot effectively communicate to parents and caregivers the hazard associated with the Subject Products if the harness is not used or is not snugly secured around the infant.

98. Because the warnings and instructions on the Subject Products are inadequate and defective, parents will continue to use the Subject Products in cribs or other enclosures.

99. Because the warnings and instructions on the Subject Products are inadequate and defective, parents will not use the harness provided or will not secure it snugly around the infant.

100. Parents and caregivers cannot and do not appreciate the hazard associated with using the Subject Products in locations other than the floor, and it is thus foreseeable that they will use the Subject Products in cribs, play yards, or other enclosures. These uses can and do result in infant death and injury.

101. Parents and caregivers cannot and do not appreciate the hazard associated with not using the harness or not securing the harness snugly, and it is foreseeable that they will use the Subject Products without securing the harness or without securing it snugly around the infant. These uses can and do result in infant death and injury.

102. The warnings on the Subject Products are inadequate and defective because while they warn against use of the Subject Products in a crib and advise users to secure the infant with the three point harness, they do not convey the gravity of the consequences of

non-compliance. Specifically, the warnings and instructions do not communicate that an infant can die if placed in a Subject Product used in a crib or other enclosure, or if the harness is not used or adequately secured. These uses can and do result in infant injury and death.

103. In addition, the warnings and instructions on the Generation Two are inadequate and defective because they do not convey the importance of ensuring, before each use, that the Velcro™ tabs are attached to the "D"-shaped rings embedded in the foam seat. The Velcro™ tabs can loosen with time and normal use of the Generation Two, allowing a child to extend his or her head over the side of the product or to fall down inside the well of the seat. It is not obvious to caregivers when these rings become loosened or unattached.

104. The effectiveness of the warnings on the Subject Products is further diminished by the advertising and marketing of the Subject Products.

105. Upon information and belief, in 2009 and thereafter, Respondent advertised the Subject Products as sleep products.

106. Upon information and belief, the advertisements encouraged consumers to use them for unattended, overnight sleep, advancing the tagline, "Everybody Sleeps!"

107. Upon information and belief, Respondent's advertisements further encouraged consumers to use the Subject Products as a traditional sleep environment, contending that the product is, "Better than a bassinet, more effective than a wedge."

108. Upon information and belief, Respondent's advertisements also promoted the Subject Products as a safe environment for infant sleep, by characterizing the Subject

Products as, "The only portable infant recliner designed for sleep, play – and peace of mind."

109. Upon information and belief, advertising for the Chill promotes the Chill as having "a 3-point safety harness anchored to the foam – no D-rings or loose cover to worry about – a contoured bucket for maximum containment and a large foam base for total stability."

110. Upon information and belief, that advertisement suggests that the Chill is safer than the Generation Two.

111. Upon information and belief, Respondent's retail partners advertised and marketed the Subject Products as a solution for babies with gastro-esophageal reflux disease that have difficulty sleeping comfortably on flat surfaces.

112. Respondents knew or should have known that its retail partners advertised and marketed the Subject Products in this manner.

113. Upon information and belief, the on-product packaging of the Generation Two Nap Nanny lists the advantages of the Subject Product as: "elevates baby, which is often recommended by doctors for babies with reflux, gas, colic, ear infections, [and] colds and stuffiness." These claims were on Subject Products sold as late as January 2011.

114. The advertising and marketing of the Subject Products conflict with the warnings and instructions that the Subject Products should not be used for unattended overnight sleep.

115. The advertising and marketing of the Subject Products conflict with the warnings and instructions that the Subject Products not be used if the infant can sit up unaided.

116. Because the advertising and marketing of the Subject Products conflict with the weight, age, and usage restrictions described on the label, the effectiveness of the warning label is diminished.

117. Even if the warnings and instructions on the Subject Products were enhanced, and the attendant advertising were changed, it is foreseeable that parents and caregivers would continue to use the products in cribs, bassinettes, and other sleep environments.

118. Parents and caregivers are likely to continue to use the Subject Products in enclosed spaces such as cribs in order to create a barrier to older siblings, pets, or pests in the home.

119. Parents and caregivers are likely to continue to use the Subject Products in cribs because cribs are traditionally viewed as safe sleeping environments.

120. Because of the lack of adequate instructions and safety warnings, a substantial risk of death and injury occurs as a result of the foreseeable use and misuse of the Subject Products.

The Type of the Risk of Injury Renders the Subject Products Defective

121. The risk of injury associated with a product may render the product defective. 16 C.F.R. § 1115.4.

122. The nature of the risk of injury includes death if a child becomes trapped between the side of the Subject Products and the bumper pad or the side of a crib.

123. The nature of the risk of injury also includes death if a child is not restrained in the seat of the Subject Products and suffocates on the interior wall or well of the seat.

124. Infants, a vulnerable population protected by the CPSA and FHSA, are exposed to risk of injury by the Subject Products.

125. The risk of injury associated with use of the Subject Products in a crib is neither obvious nor intuitive.

126. The risk of injury associated with use of the Subject Products without the harness or without tightly securing the harness is neither obvious nor intuitive.

127. Warnings and instructions cannot adequately mitigate the risk of injury and death associated with use of the Subject Products.

128. Because Respondent promoted the use of the Subject Products for unsupervised, overnight sleep, use of the Subject Products in a crib or other enclosed areas is foreseeable.

129. Use of the Subject Products without securing the harness around the infant is foreseeable.

130. The type of the risk of injury renders the Subject Products defective.

The Subject Products Create a Substantial Risk of Injury to the Public

131. The Subject Products pose a risk of injury or death to infants who may, consistent with developmentally appropriate behavior, maneuver to compromised positions either within Subject Products or partially outside Subject Products used in cribs.

132. Therefore, because the Subject Products are defective and create a substantial risk of injury, the Subject Products present a substantial product hazard within the meaning of Section 15(a)(2) of the CPSA, 15 U.S.C. § 2064(a)(2).

COUNT 2

The Subject Products are Intended for Use By Children and Contain Defects Which Create a Substantial Risk of Injury to Children Under Section 15(c)(1) of the FHSA

133. Paragraphs 1 through 132 are hereby realleged and incorporated by reference as though fully set forth herein.

134. Upon information and belief, the Subject Products are an article intended for use by children as young as newborns. Respondent has marketed, and continues to promote, the Subject Products as appropriate for use by infants weighing eight pounds or more until the infant can sit up unassisted.

135. The Subject Products contain a design defect that is present in all models of the Subject Products.

136. The harness designs in the Generation One and the Generation Two are defective because each design fails to adequately restrain the infant user.

137. The harness design in the Generation Two is also defective because the "D"-shaped ring in the foam base must be secured after the cover is changed, and can also become loose with regular use of the product. Caregivers are not informed adequately of the importance of securing the harness straps to the "D"-shaped rings embedded in the foam seat base and may use the product without securing the "D"-shaped rings or ensuring that they are adequately tightened before each use.

138. The harness design in the Chill is defective because the double-threaded buckles inhibit a caregiver's ability to secure the harness around the infant user, thereby reducing the effectiveness of the harness and the likelihood of use of the harness by the caregiver.

139. The harness design in the Chill is also defective because the harness straps and buckles are not attached to the base and may be removed from the Chill. The buckles are sewn into a small, removable crotch pad that Respondent advises in its User Guide should be removed as needed to be machine washed.

140. It is foreseeable that users frequently will wash the crotch pad of the Chill. Removing the pad to do so renders the Chill's restraint system inoperable. It is also foreseeable that the small, removable crotch pad may be lost, rendering the Chill's restraint system inoperable.

141. Because of the cost of the Chill, it is likely that users will continue to use them or sell them even if they lose the small, removable crotch pad with attached buckles. Because Respondent has stated that it has "closed [its] doors," users will be unable to obtain replacement crotch pads with buckles, and may continue to use the Chill even though it lacks a crotch pad and buckles, rendering the Chill's restraint system inoperable, thereby endangering users.

142. Upon information and belief, Respondent has distributed over 160,000 Subject Products into U.S. commerce and the Chill continues to be available for purchase through some of Respondent's retail partners.

143. Upon information and belief, the severity of the risk associated with use of all of the Subject Products is extremely high, as five infants have died while using the Subject Products.

144. The Subject Products contain a defect, which creates a substantial risk of injury to children because of the pattern of defect, the number of such defective articles distributed

in commerce and the severity of the risk within the meaning of Section 15(c)(1) of the FHSA, 15 U.S.C. §1274(c)(1).

Relief Sought

Wherefore, in the public interest, Complaint Counsel requests that the Commission:

A. Determine that the Subject Products present a "substantial product hazard" within the meaning of Section 15(a)(2) of the CPSA, 15 U.S.C. § 2064(a)(2), and/or present a "substantial product hazard" within the meaning of Section 15(a)(1) of the CPSA, 15 U.S.C. § 2064(a)(1).

B. Determine that the Subject Products contain a defect, which creates a substantial risk of injury to children because of the pattern of defect, the number of such articles distributed in commerce, the severity of the risk, or otherwise, within the meaning of Section 15(c)(1) of the FHSA, 15 U.S.C. § 1274(c)(1).

C. Determine that extensive and effective public notification under Section 15(c) of the CPSA, 15 U.S.C. § 2064(c), is required to protect the public and children adequately from the substantial product hazard presented by the Subject Products, and order Respondent under Section 15(c) of the CPSA, 15 U.S.C. § 2064(c) to:

(1) Cease any remaining distribution of the product to other distributors, wholesalers or retailers;

(2) Notify all persons that transport, store, distribute or otherwise handle the Subject Products, or to whom such products have been transported, sold, distributed or otherwise handled, to immediately cease distribution of the Subject Products;

(3) Notify appropriate state and local public health officials;

(4) Give prompt public notice of the defects in the Subject Products, including

the incidents and injuries associated with use of the Subject Products including posting clear and conspicuous notice on Respondent's website, and providing notice to any third party website on which Respondent has placed the Subject Products for sale, and provide further announcements in languages other than English and on radio and television;

(5) Mail notice to each distributor or retailer of the Subject Products; and

(6) Mail notice to every person to whom the Subject Products were delivered or sold;

D. Determine that extensive and effective public notification under Section 15(c)(1)(A) of the FHSA, 15 U.S.C. § 1274(c)(1), is required to protect the public and children adequately from the substantial product hazard presented by the Subject Products, and order Respondent under Section 15(c) of the FHSA, 15 U.S.C. § 1274(c)(1)(A) to:

(1) To give public notice that such defective toy or article contains a defect which creates a substantial risk of injury to children;

(2) To mail such notice to each person who is a manufacturer, distributor, or dealer of such toy or article; and

(3) To mail such notice to every person to whom the person giving notice knows such toy or article was delivered or sold.

E. Determine that action under Section 15(d) of the CPSA, 15 U.S.C. § 2064(d) and Section 15(c)(2) of the FHSA, 15 U.S.C. § 1274(c)(2), is in the public interest and additionally order Respondent to:

(1) Refund consumers the purchase price of the Subject Products;

(2) Make no charge to consumers and to reimburse consumers for any reasonable and foreseeable expenses incurred in availing themselves of any remedy provided under any Commission Order issued in this matter, as provided by Section 15 U.S.C. § 2064(e)(1) of the CPSA and Section 15 U.S.C. § 1274(d)(1) of the FHSA;

(3) Reimburse retailers for expenses in connection with carrying out any Commission Order issued in this matter, including the costs of returns, refunds and/or replacements, as provided by Section 15(e)(2) of the CPSA, 15 U.S.C. § 2064(e)(2) and Section 15(d)(2) of the FHSA, 15 U.S.C. § 1274(d)(2);

(4) Submit a corrective action program satisfactory to the Commission, within ten (10) days of service of the Final Order, directing that actions specified in Paragraphs C(1) through (6) and D(1) through (3) above be taken in a timely manner;

(5) To submit monthly reports, in a format satisfactory to the Commission, documenting the progress of the corrective action program;

(6) For a period of five (5) years after issuance of the Final Order in this matter, to keep records of its actions taken to comply with Paragraphs C(1) through (6) and D(1) through (3) above, and supply these records to the Commission for the purpose of monitoring compliance with the Final Order; and

(7) For a period of five (5) years after issuance of the Final Order in this matter, to notify the Commission at least sixty (60) days prior to any change in its business (such as incorporation, dissolution, assignment, sale, or petition for bankruptcy) that results in, or is intended to result in, the emergence of a successor

corporation, going out of business, or any other change that might affect compliance obligations under a Final Order issued by the Commission in this matter.

F. Order that Respondent shall take other and further actions as the Commission deems necessary to protect the public health and safety and to comply with the CPSA and FHSA.

ISSUED BY ORDER OF THE COMMISSION:

Dated this 25th day of January, 2013

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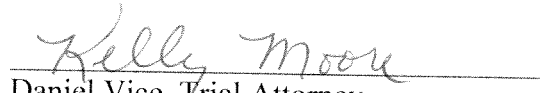

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CERTIFICATE OF SERVICE

I certify that I have served the foregoing Motion, Memorandum, Amended Complaint and Proposed Order on all parties and participants of record in these proceedings by emailing a courtesy copy and by mailing, postage prepaid a copy to each on January 25, 2013.

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