



April 19, 2023

Marc C. Sanchez
Regulatory Counsel
KKL International, Inc.
1717 Pennsylvania Ave NW, Suite 1025
Washington, DC 20006-3951

Re: Docket No. FDA-2022-P-3158

Dear Mr. Sanchez,

On December 8, 2022, the Food and Drug Administration (FDA) received from KKL International, Inc. (“petitioner”) a petition for administrative stay under 21 C.F.R. § 10.35 pending completion of supervisory review under 21 C.F.R. § 10.75. The petition seeks a stay of a Refuse to Accept (RTA) letter issued on November 8, 2022, for a number of Premarket Tobacco Product Applications (“PMTA”) received by FDA on May 13, 2022, pursuant to section 910(b) of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”).

FDA has reviewed the petition, the request for supervisory review, the RTA letter, and the applicable regulations. For the reasons described below, FDA denies the petition.

BACKGROUND

On May 13, 2022, KKL submitted PMTAs for the following products. They were assigned STN PM0005588.PD1-PD20:

- ONEE MAX 6500 puffs - Classic Tobacco
- ONEE MAX 6500 puffs - Menthol
- ONEE MAX 6500 puffs - Strawberry Delight
- ONEE MAX 6500 puffs - Arctic Lush Ice
- ONEE MAX 6500 puffs - Passion Freeze
- ONEE MAX 6500 puffs - Frozen Cranberry Grape
- ONEE MAX 6500 puffs - Arctic Blue Razz
- ONEE MAX 6500 puffs - Rainbow Freeze
- ONEE MAX 6500 puffs - Arctic Devine
- ONEE MAX 6500 puffs - Fro-Yo
- ONEE MAX 6500 puffs - Frozen Butter Banana
- ONEE MAX 6500 puffs - Frozen Mixed Fruit
- ONEE MAX 6500 puffs - Chewy Gum Freeze
- ONEE MAX 6500 puffs - Frozen Green Apple
- ONEE MAX 6500 puffs - Straw Shake

- ONEE MAX 6500 puffs - Blue Shake
- ONEE MAX 6500 puffs - Bubble Tea
- ONEE MAX 6500 puffs - Tropical Mixed Fruity
- ONEE MAX 6500 puffs - Fruity Creamy Vanilla
- ONEE MAX 6500 puffs - Double Yellow Pops

KKL also submitted PMTAs for the following products that were assigned STN PM0005592.PD1-PD28:

- ONEE MAX 6000 puffs - Classic Tobacco
- ONEE MAX 6000 puffs - Menthol
- ONEE MAX 6000 puffs - Cool Mint
- ONEE MAX 6000 puffs - Pitchy Delight
- ONEE MAX 6000 puffs - Melon Ice
- ONEE MAX 6000 puffs - Lush Ice
- ONEE MAX 6000 puffs - Vintage
- ONEE MAX 6000 puffs - Blueberry Cream
- ONEE MAX 6000 puffs - Rainbow
- ONEE MAX 6000 puffs - Apples
- ONEE MAX 6000 puffs - Honeydew Punch
- ONEE MAX 6000 puffs - Pink Lemonade
- ONEE MAX 6000 puffs - Cherry Lemonade
- ONEE MAX 6000 puffs - Strawberry Delight
- ONEE MAX 6000 puffs - Blue Razz Ice
- ONEE MAX 6000 puffs - Fruit Bear
- ONEE MAX 6000 puffs - Devine
- ONEE MAX 6000 puffs - Pear Cotton
- ONEE MAX 6000 puffs - Apple Blue Razz
- ONEE MAX 6000 puffs - Watermelon Cream
- ONEE MAX 6000 puffs - Blueberry Ice Cream
- ONEE MAX 6000 puffs - Rainbow Candy
- ONEE MAX 6000 puffs - Strawberry
- ONEE MAX 6000 puffs - Yummy Bear
- ONEE MAX 6000 puffs - Pear Cotton Candy
- ONEE MAX 6000 puffs - Watermelon Ice Cream
- ONEE MAX 6000 puffs - Spearmint
- ONEE MAX 6000 puffs - Strawberry Cream

KKL also submitted PMTAs for the following products that were assigned STN PM0005596.PD1-PD20:

- ONEE STICK 3000 puffs - Virginia Tobacco
- ONEE STICK 3000 puffs - Menthol
- ONEE STICK 3000 puffs - Cool Mint
- ONEE STICK 3000 puffs - Strawberry Cream

- ONEE STICK 3000 puffs - Pink Lemonade
- ONEE STICK 3000 puffs - Red Apple
- ONEE STICK 3000 puffs - Raspberry Watermelon Lemonade
- ONEE STICK 3000 puffs - Sour Apple
- ONEE STICK 3000 puffs - Blueberry Cream
- ONEE STICK 3000 puffs - Rainbow
- ONEE STICK 3000 puffs - Tropical Ice
- ONEE STICK 3000 puffs - Devine
- ONEE STICK 3000 puffs - Pear Cotton
- ONEE STICK 3000 puffs - Pitchy Delight
- ONEE STICK 3000 puffs - Lush Ice
- ONEE STICK 3000 puffs - Watermelon Cream
- ONEE STICK 3000 puffs - Blue Razz Ice
- ONEE STICK 3000 puffs - Fruity Creamy Vanilla
- ONEE STICK 3000 puffs - Red Ice
- ONEE STICK 3000 puffs - Vintage

KKL also submitted PMTAs for the following products that were assigned STN PM0005629.PD1-PD20:

- ONEE STICK 2500 puffs - Classic Tobacco
- ONEE STICK 2500 puffs - Menthol
- ONEE STICK 2500 puffs - Arctic Lush Ice
- ONEE STICK 2500 puffs - Arctic Peach Delight
- ONEE STICK 2500 puffs - Milk Tea Latte
- ONEE STICK 2500 puffs - Arctic Tropical Mango
- ONEE STICK 2500 puffs - Frozen Butter Banana
- ONEE STICK 2500 puffs - Strawberry Kiwi Freeze
- ONEE STICK 2500 puffs - Taro Bobo
- ONEE STICK 2500 puffs - Blue Shake
- ONEE STICK 2500 puffs - Blueberry Ice
- ONEE STICK 2500 puffs - Tangerine Freeze
- ONEE STICK 2500 puffs - Chewy Gum Freeze
- ONEE STICK 2500 puffs - Chilled Creamy Vanilla
- ONEE STICK 2500 puffs - Apple Blue Razz Freeze
- ONEE STICK 2500 puffs - Strawnana
- ONEE STICK 2500 puffs - Cranberry Grape Freeze
- ONEE STICK 2500 puffs - Passion Freeze
- ONEE STICK 2500 puffs - Frozen Pina Colada
- ONEE STICK 2500 puffs - French Vanilla Coffee

KKL also submitted PMTAs for the following products that were assigned STN PM0005634.PD1-PD20:

- ONEE MAX 5000 puffs - Classic Tobacco

- ONEE MAX 5000 puffs - Menthol
- ONEE MAX 5000 puffs - Sour Apple Ice
- ONEE MAX 5000 puffs - Lush Ice
- ONEE MAX 5000 puffs - Melontime Ice
- ONEE MAX 5000 puffs - Vintage
- ONEE MAX 5000 puffs - Blue Razz Ice
- ONEE MAX 5000 puffs - Rainbow
- ONEE MAX 5000 puffs - Pink Lemonade
- ONEE MAX 5000 puffs - Red Ice
- ONEE MAX 5000 puffs - Blueberry Ice
- ONEE MAX 5000 puffs - Apples
- ONEE MAX 5000 puffs - Fruit Bear
- ONEE MAX 5000 puffs - Devine
- ONEE MAX 5000 puffs - Apple Blue Razz
- ONEE MAX 5000 puffs - Pear Cotton
- ONEE MAX 5000 puffs - Honeydew Punch
- ONEE MAX 5000 puffs - Strawberry Ice
- ONEE MAX 5000 puffs - Cool Mint
- ONEE MAX 5000 puffs - Pitchy Delight

KKL also submitted PMTAs for the following products that were assigned STN PM0005637.PD1-PD20:

- ONEE STICK 5200 puffs - Classic Tobacco
- ONEE STICK 5200 puffs - Menthol
- ONEE STICK 5200 puffs - Frozen Green Apple
- ONEE STICK 5200 puffs - Arctic Lush Ice
- ONEE STICK 5200 puffs - Red Ocean Freeze
- ONEE STICK 5200 puffs - Frozen Mixed Fruit
- ONEE STICK 5200 puffs - Milk Tea Latte
- ONEE STICK 5200 puffs - Arctic Blue Razz
- ONEE STICK 5200 puffs - Rainbow Freeze
- ONEE STICK 5200 puffs - Frozen Butter Banana
- ONEE STICK 5200 puffs - Blue Shake
- ONEE STICK 5200 puffs - Frozen Fruit Bear
- ONEE STICK 5200 puffs - Frozen Classic Bubble
- ONEE STICK 5200 puffs - Double Yellow Pops
- ONEE STICK 5200 puffs - Frozen Pear Cotton
- ONEE STICK 5200 puffs - Fro-yo
- ONEE STICK 5200 puffs - Frozen Pina Colada
- ONEE STICK 5200 puffs - Arctic Peach Delight
- ONEE STICK 5200 puffs - Frozen Melontime
- ONEE STICK 5200 puffs - Chewy Gum Freeze

KKL also submitted PMTAs for the following products that were assigned STN PM0005640.PD1-PD20:

- ONEE STICK 3500 puffs - Classic Tobacco
- ONEE STICK 3500 puffs - Menthol
- ONEE STICK 3500 puffs - Arctic Lush Ice
- ONEE STICK 3500 puffs - Arctic Peach Delight
- ONEE STICK 3500 puffs - Milk Tea Latte
- ONEE STICK 3500 puffs - Frozen Pink Lemonade
- ONEE STICK 3500 puffs - Apple Blue Razz Freeze
- ONEE STICK 3500 puffs - Arctic Blue Razz
- ONEE STICK 3500 puffs - Classic Bubble Freeze
- ONEE STICK 3500 puffs - Arctic Devine
- ONEE STICK 3500 puffs - Frozen Cranberry Grape
- ONEE STICK 3500 puffs - Frozen Pina Colada
- ONEE STICK 3500 puffs - Chilled Creamy Vanilla
- ONEE STICK 3500 puffs - Frozen Blueberry
- ONEE STICK 3500 puffs - Butter Crunch
- ONEE STICK 3500 puffs - Frozen Mixed Fruit
- ONEE STICK 3500 puffs - Freeze Lush Menthol
- ONEE STICK 3500 puffs - Passion Freeze
- ONEE STICK 3500 puffs - Arctic Tropical Mixed Fruit
- ONEE STICK 3500 puffs - French Vanilla Coffee

KKL also submitted PMTAs for the following products that were assigned STN PM0005643.PD1-PD20:

- ONEE STICK 4000 puffs - Virginia Tobacco
- ONEE STICK 4000 puffs - Menthol
- ONEE STICK 4000 puffs - Frozen Green Apple
- ONEE STICK 4000 puffs - Arctic Lush Ice
- ONEE STICK 4000 puffs - Arctic Red Ocean
- ONEE STICK 4000 puffs - Frozen Cranberry Grape
- ONEE STICK 4000 puffs - Arctic Blue Razz
- ONEE STICK 4000 puffs - Rainbow Freeze
- ONEE STICK 4000 puffs - Classic Bubble Freeze
- ONEE STICK 4000 puffs - Frozen Butter Banana
- ONEE STICK 4000 puffs - Bubble Gum Freeze
- ONEE STICK 4000 puffs - Frozen Fruit Bear
- ONEE STICK 4000 puffs - Chewy Gum Freeze
- ONEE STICK 4000 puffs - Blueberry Ice
- ONEE STICK 4000 puffs - Milk Tea Latte
- ONEE STICK 4000 puffs - Fro-yo
- ONEE STICK 4000 puffs - Arctic Pina Colada

- ONEE STICK 4000 puffs - Arctic Peach Delight
- ONEE STICK 4000 puffs - Vanilla Delight
- ONEE STICK 4000 puffs - Strawberry Kiwi Freeze

KKL also submitted PMTAs for the following products that were assigned STN PM0005644.PD1-PD20:

- ONEE STICK 2000 puffs - Virginia Tobacco
- ONEE STICK 2000 puffs - Menthol
- ONEE STICK 2000 puffs - Vintage
- ONEE STICK 2000 puffs - Melontime
- ONEE STICK 2000 puffs - Cranberry Grape
- ONEE STICK 2000 puffs - Blueberry Ice
- ONEE STICK 2000 puffs - Fruit Bear
- ONEE STICK 2000 puffs - Devine
- ONEE STICK 2000 puffs - Tuity Fruit
- ONEE STICK 2000 puffs - Blue Cloud
- ONEE STICK 2000 puffs - Tangerine
- ONEE STICK 2000 puffs - Cool Mint
- ONEE STICK 2000 puffs - Lush Ice
- ONEE STICK 2000 puffs - Pitchy Delight
- ONEE STICK 2000 puffs - Raspberry Lemonade
- ONEE STICK 2000 puffs - Tropical Ice
- ONEE STICK 2000 puffs - Blue Razz Ice
- ONEE STICK 2000 puffs - Strawberry Kiwi
- ONEE STICK 2000 puffs - Red Ice
- ONEE STICK 2000 puffs - Pear Cotton

KKL also submitted PMTAs for the following products that were assigned STN PM0005652.PD1-PD20:

- ONEE STICK 5500 puffs - Virginia Tobacco
- ONEE STICK 5500 puffs - Menthol
- ONEE STICK 5500 puffs - Frozen Green Apple
- ONEE STICK 5500 puffs - Arctic Blue Razz
- ONEE STICK 5500 puffs - Red Ocean Freeze
- ONEE STICK 5500 puffs - Arctic Lush Ice
- ONEE STICK 5500 puffs - Blueberry Freeze
- ONEE STICK 5500 puffs - Arctic Pina Colada
- ONEE STICK 5500 puffs - Cranberry Grape Freeze
- ONEE STICK 5500 puffs - Mint Freeze
- ONEE STICK 5500 puffs - Arctic Peach Delight
- ONEE STICK 5500 puffs - Apple Blue Razz Freeze
- ONEE STICK 5500 puffs - Milk Tea Latte
- ONEE STICK 5500 puffs - Peach Mango Lemon

- ONEE STICK 5500 puffs - Tangerine Freeze
- ONEE STICK 5500 puffs - Strawberry Kiwi Freeze
- ONEE STICK 5500 puffs - Strawberry Mango
- ONEE STICK 5500 puffs - Vintage
- ONEE STICK 5500 puffs - Strawberry Cream
- ONEE STICK 5500 puffs - French Vanilla Coffee

KKL also submitted PMTAs for the following products that were assigned STN PM0005657.PD1-PD20:

- BIRKINZ 2500 - Virginia Tobacco
- BIRKINZ 2500 - Menthol
- BIRKINZ 2500 - Icy Grapevine
- BIRKINZ 2500 - Kiwi Komodo
- BIRKINZ 2500 - Razzle Dazzle Pom Pom
- BIRKINZ 2500 - Icy Watermelon-licous
- BIRKINZ 2500 - Dragon Mango Lemonade
- BIRKINZ 2500 - Garden Mint
- BIRKINZ 2500 - Raspberry Denim
- BIRKINZ 2500 - Rainbowlicious
- BIRKINZ 2500 - Strawberry Glacier
- BIRKINZ 2500 - Icy Watermelon-licous
- BIRKINZ 2500 - Blood Apple
- BIRKINZ 2500 - Dark Hydra Chill
- BIRKINZ 2500 - Strawbrizzle Lemon
- BIRKINZ 2500 - Glazed Strawberry
- BIRKINZ 2500 - Ice Ice Baby
- BIRKINZ 2500 - Icy Mangos
- BIRKINZ 2500 - Icy Rainbow
- BIRKINZ 2500 - Icy Green Apple

On May 14, 2022, KKL also submitted PMTAs for the following products that were assigned STN PM0005683.PD1-PD18:

- SPACE CADET - Melon Ice
- SPACE CADET - Pineapple Orange and Lavender
- SPACE CADET - Grape Ice
- SPACE CADET - Strawberry Ice
- SPACE CADET - Blood Orange Banana Kiwi
- SPACE CADET - Peach Mango Guava
- SPACE CADET - Pitaya Lemon
- SPACE CADET - Orange Ice
- SPACE CADET - Watermelon and Melon
- SPACE CADET - Blue Raspberry
- SPACE CADET - Mint

- SPACE CADET - Energy Drink
- SPACE CADET - Strawberry Kiwi
- SPACE CADET - Orange Mango
- SPACE CADET - Cranberry Lime
- SPACE CADET - Sour Apple
- SPACE CADET - Peach Ice
- SPACE CADET - Bubblegum

KKL also submitted PMTAs for the following products that were assigned STN PM0005687.PD1-PD16:

- BIRKINZ 4000 - Blue Razz Ice
- BIRKINZ 4000 - Grape Ice
- BIRKINZ 4000 - Strawberry ice
- BIRKINZ 4000 - Watermelon Ice
- BIRKINZ 4000 - Banana Ice
- BIRKINZ 4000 - Energy Drink
- BIRKINZ 4000 - Pink lemon
- BIRKINZ 4000 - Rainbow
- BIRKINZ 4000 - Mango Ice
- BIRKINZ 4000 - Blueberry Ice
- BIRKINZ 4000 - Refreshing Mint
- BIRKINZ 4000 - Rose Ice Cream
- BIRKINZ 4000 - Watermelon Rum Punch
- BIRKINZ 4000 - Lemon Mojito
- BIRKINZ 4000 - Apple Energy
- BIRKINZ 4000 - Cherry Cola

On July 22, 2022, KKL submitted two sets of additional documents. The first set contained FDA Form 4057a, fourteen versions of FDA Form 4057, and fourteen Excel spreadsheets. These were assigned STN PM0006697. The second submission contained FDA Form 4057a. This was assigned STN PM0006719.

On November 4, 2022, KKL submitted a cover letter, FDA Form 4057a, and twenty-four versions of FDA Form 4057b. These were assigned STN PM0007073.

On November 8, 2022, FDA issued Refuse to Accept (RTA) letters for all 262 products.

On December 5, 2022, KKL filed the request for supervisory review at issue here.

On December 8, 2022, FDA received the petition described above. In a letter to petitioner sent on December 9, 2022, Supervisory Administrative Proceedings Officer Karen Malvin acknowledged receipt of the petitions (“Acknowledgment Letter”).

DISCUSSION

The petitioner seeks a stay of administrative action pursuant to 21 C.F.R. § 10.35.¹ The petitioner seeks a stay “for an indefinite period of time due to the indeterminable timeframe for the Center for Tobacco Products to complete a review under 21 CFR § 10.75.”²

The request for supervisory review pursuant to 21 C.F.R. § 10.75 (“appeal”) of the RTA letter issued to KKL International, Inc., was completed on April 12, 2023.³ Therefore, the request for a stay pending the supervisory review is moot.

CONCLUSION

For the foregoing reasons, the Petition for Administrative Stay of Action submitted under 21 C.F.R. § 10.35 is denied as moot.

Sincerely,

Brian A. King, Ph.D., M.P.H.
Center Director
Center for Tobacco Products

¹ *Petition for Stay of Action*, dated December 5, 2022, page 1.

² *Id.*

³ *Response to Request for Supervisory Review – PM0005683, PM0005687, PM0005588, PM0005592, PM0005596, PM0005629, PM0005634, PM0005637, PM0005640, PM0005643, PM0005644, PM0005652, and PM0005657 (AP0000210)*, dated April 12, 2023.