AFFIDAVIT

SAMPLE NO.

STATE OF
CALIFORNIA

COUNTY OF
Sonoma County

Before me, Aliza Chalapong, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared John Z. Fitch in the county and state aforesaid, who, being duly sworn, deposes and says:

My name is John Z. Fitch. I am the owner of TDB Liquids LLC. As such, I am knowledgeable of the receiving, purchasing, storage, manufacturing, commercial marketing and distribution of tobacco and non-tobacco-derived nicotine products at my firm.

My firm is not currently importing, or commercially marketing and distributing into the United States, any non-tobacco-derived nicotine products.

My firm has not submitted premarket application(s) for any commercially marketed and distributed finished non-tobacco-derived nicotine (NTN) products by the May 14, 2022 deadline.

On 08/31/222, FDA Investigator Aliza Chalapong gave me information regarding manufacturing obligations and FDA's current enforcement priorities, including FDA's Guidance for Industry: "Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization" and "Requirements for Products Made with Non-Tobacco Nicotine Take Effect April 14."

Additionally, FDA Investigator Aliza Chalapong explained that on March 15, 2022, the President signed legislation to amend the FD&C Act to extend FDA's jurisdiction to products "containing nicotine from any source," not just nicotine derived from tobacco. See Consolidated Appropriations Act, 2022, Public Law 117-103, Division P, Subtitle B. Specifically, this legislation expanded the definition of "tobacco product" under section 201(rr) of the FD&C Act (21 U.S.C. § 321(rr)) to include products containing nicotine from any source. Among other things, the legislation subjects tobacco products containing nicotine from any source to FDA's tobacco product authorities, which renders such products subject to the requirements of the FD&C Act and its implementing regulations. The tobacco product provisions of the legislation went into effect on April 14, 2022. As of April 14, 2022, tobacco products containing nicotine from any source must be in compliance with all applicable requirements for tobacco products under the FD&C Act and its implementing regulations, and such products not in compliance with these requirements are subject to enforcement.

AFFIANT'S SIGNATURE AND TITLE

JF owner

owner JF

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

TBD Liquids LLC, 997 Piner Rd, Santa Rosa, CA, 95403

Subscribed and sworn to before me at Santa Rosa, CA *(City and State)*,

this 31st **day of** August, **20** 22.

Aliza Chalapong *(Employee's Signature)*

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.

STATE OF
CALIFORNIA

COUNTY OF
Sonoma County

Before me, Aliza Chalapong, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared John Z. Fitch in the county and state aforesaid, who, being duly sworn, deposes and says:

My firm has submitted premarket application(s) for commercially marketed and distributed finished tobacco-derived nicotine products by the September 9, 2020 deadline. Investigator Chalapong provided me with a copy of the FDA acceptance letter dated August 13, 2021 for PMTA STN #PM0004179. I have contacted the FDA on numerous occasions trying to ascertain status and support for my small business, and have not received any relevant informational responses.

On 08/30/2022, I provided Investigator Aliza Chalapong with a copy of my PMTA that was submitted via FDA esubmitter on 09/09/2020.

Additionally, Investigator Chalapong explained that on July 12, 2019, the United States District Court for the District of Maryland ordered the FDA to require manufacturers of deemed new tobacco products that were on the market as of August 8, 2016 to submit applications for premarket review to FDA by May 12, 2020. On April 22, 2020, the court granted a motion for a 120-day extension (until September 9, 2020) in light of the coronavirus pandemic.

My firm continues to manufacture tobacco-derived nicotine e-liquids under my TBD brand. We sell direct to the consumer via online sale from my website : www.tbdliquids.com. All orders are delivered by the USPS with the added Adult Signature Required service. This service instructs the USPS to verify age with identification to accept the package(s).

I have provided Investigator Chalapong with a supplier list, product list, Signature Lab Reports, Quality Control Procedures, QA Receiving, Product Recall Plan, PMTA, Nicotine River purchase history, KIC Chemicals Invoice #3014662 and COA, General Certificates of Conformity (Bottles), FDA Letter Response 2019, Complaints Process, Attorney Opinion Letter, and KIC Sales Order #7013572

I also demonstrated the age verification process on our website that customers must undertake in order to purchase products. I have pulled the promotional tshirts from sale and ceased including the menu cards from distribution due to lack of warning statement.

Owner

AFFIANT'S SIGNATURE AND TITLE

JF Owner JF

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

TBD Liquids LLC, 997 Piner Rd, Santa Rosa, CA, 95403

Subscribed and sworn to before me at Santa Rosa, CA *(City and State)*,

this 31st **day of** August, **20** 22.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.

STATE OF
CALIFORNIA

COUNTY OF
Sonoma County

Before me, Aliza Chalapong, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared John Z. Fitch in the county and state aforesaid, who, being duly sworn, deposes and says:

I also provided batch records as listed below:

TBD Jolly Watermelon Salt 15 MG
- Packing Slip #152992, dated 08/30/2022
- 3 labels for Jolly Watermelon Salt 15mg
- Daily Mixing Log for 08/19/2022
- Recipe
- USPS Tracking 940551129837013698273 9

TBD Mango Salt 30 mg
- Packing Slip #152944, dated 08/30/2022
- 3 labels for TBD Mango Salt
- Daily Mixing Log for 08/29/2022
- Recipe
- USPS Tracking 9400111298370136120572

TBD Blue Raspberry Salt 30 mg
- Packing Slip #152949, dated 08/30/2022
- 3 labels for TBD Blue Raspberry Salt 30 mg
- Daily Mixing Log for 08/22/2022
- Recipe
- USPS Tracking 9400111298370136183348

I read this statement, understand it to the best of my ability, and based on this understanding agree that it is true. JF

owner

AFFIANT'S SIGNATURE AND TITLE

JF owner

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

TBD Liquids LLC, 997 Piner Rd, Santa Rosa, CA, 95403

Subscribed and sworn to before me at Santa Rosa, CA *(City and State)*,

this 31st **day of** August, **20** 22.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.