KELLER AND HECKMAN LLP
Serving Business through Law and Science®

Tobacco and Vapor Product Manufacturing Establishment Audit and Mock Inspection Program – Pre-Registration Form

Administrative Information

Company Name: _____

Address: _____

City, State, Zip: _____

Size of Facility: _____ sq. ft. Number of Employees: _____ (full-time equivalent)

Product and Facility Information

Type of Product(s) (*check all that apply – categories include accessories*):

□ Advanced Personal Vaporizer/Kit
□ E-Cigars
□ Dissolvables
□ Hookah
□ Roll-Your-Own
□ Other Electronic Nicotine Delivery System
□ Chewing Tobacco
□ Cigarettes
□ Dry snuff
□ E-Liquids
□ Vape Pen/Kit
□ Cigars
□ E-Cigarettes
□ Filters
□ Pipe Tobacco
□ Waterpipe Tobacco

□ Other _____

Type of Operation(s) (*check all that apply*):

□ Blending
□ Manufacturing
□ Reconstituting Tobacco
□ Packaging
□ Labeling
□ Saucing (or casing)
□ Storing
□ Testing

□ Other _____

Special Access Requirements:
(Cleanroom, Laboratory, etc.)

_____
_____
_____
_____

Number of individual (discrete) products offered for sale: _____

Regulatory Information

Prior History of FDA Registration, Inspection, and/or Communication (approximate date(s)):

1) Have you registered your facility and listed your products (U.S. manufacturing establishments only)? □ Yes □ No
   If so, please provide your date of registration and FEI Number: _____

2) Have you submitted your health document notification? □ Yes □ No
   If so, please provide the date of submission and whether you submitted any health documents:
   _____

3) Have you provided, or are you in the process of providing, ingredient reports for your products?
   □ Yes □ No If so, please provide an approximate date of submission: _____

4) Do you have documentation of the pre-August 8, 2016 marketing status of your product(s)?
   □ Yes □ No

5) Please provide the date(s) of any prior FDA or other inspection(s):
   _____

Pre-Registration Information

Est. Number of Employees Attending Training: _____

Training and Facility Audit Visit Requested:

□ **As soon as possible**, or*:*

□ January-March □ April-June □ July-September □ October-December

Supplemental Training and Auditing (*check all that apply*):

□ *I would like to include a training/auditing component on environmental and waste management regulations pursuant to the Federal Resource Conservation and Recovery Act (RCRA).*

□ *I would like to include a training/auditing component on workplace safety regulations pursuant to the Occupational Safety and Health Act (OSH Act).*

Additional Comments

Please provide any additional comments or questions in this space. **Please do not include any sensitive or Confidential Business Information (CBI) in this form**.

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Sign and Return

To complete pre-registration for Keller and Heckman's Audit and Inspection Program, please sign and date the form below, and return electronically to chowdhury@khlaw.com, send via fax to (202) 434-4646, or mail to:

Keller and Heckman LLP
Attn: Azim Chowdhury
1001 G Street NW, Suite 500 West
Washington, D.C. 20001

Pre-registration forms will be acknowledged within five business days of receipt, and a written proposal will follow shortly thereafter.

Name of Authorized Representative: _____

E-Mail: (□ *preferred method of communication*): _____

Phone Number: _____

Signature: _____ Date: _____