VTA
VAPOR TECHNOLOGY ASSOCIATION

VTA GUIDANCE

February 3, 2017

FDA Ingredient Listings for Finished E-Liquid Products
Who? When? What? How?

On **Wednesday, February 8, 2017**, VTA will be hosting a webinar that will be conducted by two FDA attorneys from Kleinfeld, Kaplan & Becker, LLP
Stacy Ehrlich & **Will Woodlee**

Ms. Ehrlich's and Mr. Woodlee's practices focus on counseling and advocating on behalf of food, dietary supplement, cosmetic, pharmaceutical, medical device, tobacco, and consumer product companies on regulatory and advertising law matters. Since early in the legislative process of the Family Smoking Prevention and Tobacco Control Act, KKB has advised industry members now subject to FDA regulation under the 2009 law.

In this Guidance

INTREPID

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WHAT: **FDA INGREDIENT LISTING SUBMISSIONS FOR FINISHED E-LIQUID PRODUCTS**

WHEN: February 8, 2017 – 3:00 p.m. (eastern) / 2:00 p.m. (central) / 12:00 p.m. (pacific)

REGISTER: **https://attendee.gotowebinar.com/register/1114376305931264257**

NOTES: **Once you register, you will receive an email with log-in and dial-in instructions. Please log in (or dial in) early so that we may start the webinar on time.**

QUESTIONS: Email Tony Abboud at: **abboud@vaportechnology.org**

INTRODUCTION

FDA requires each finished tobacco product manufacturer or importer to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to e-liquids by brand and by quantity in each brand and sub-brand.

This guidance provides further information on determining whether you are required to submit an ingredient listing and, if so, when, how, and what you should submit.

WHO NEEDS TO SUBMIT?

DO I NEED TO SUBMIT INGREDIENT LISTINGS?

To answer this question, please ask yourself the following:

Question 1: Do I manufacture, import, or package/label (or repackage/relabel) finished tobacco products? To answer this question, please first consider the following:

- A *finished tobacco product* is a tobacco product, including all components and parts, sealed in final packaging intended for consumer use.
- A finished product does not include a tobacco product sold or distributed solely for further manufacturing.
- Components and parts that are sold separately from other tobacco products or in kits are considered finished tobacco products if they are sold in final packaging intended for consumer use (e.g., e-liquids, cartridges, atomizers, e-cigarette batteries, cartomizers, clearomizers, tanks, coils, and e-liquid flavorings).

- If no, based on FDA's current enforcement policies, then you do not need to submit ingredient listings to FDA at this time.
- If yes, then go to the next question.

Question 2: Is my finished tobacco product manufactured in a foreign country?

- If no, as the domestic manufacturer, you must submit ingredient information for the product. Continue to the next question.

- If yes, either the foreign manufacturer or the importer of the finished tobacco product must submit ingredient information for the product. The foreign manufacturer and importer should coordinate to ensure that the ingredient listing reports are prepared and submitted in a timely manner. Continue to the next question.

WHEN MUST I SUBMIT?

WHEN MUST I SUBMIT INGREDIENT LISTINGS?

To answer this question, please ask yourself the following:

Question 3: Was my finished tobacco product on the market as of August 8, 2016?

- If your answer to Question 3 is yes, then answer the following:

    - Question 3a: Am I a small-scale tobacco product manufacturer (i.e., does my company, and each entity that it controls, is controlled by, or is under common control with, combined employ 150 or fewer full-time equivalent employees and have annual total revenues of $5 million or less)?

        - If your answer to Question 3a is yes, then FDA must receive your product's ingredient listing by February 8, 2018.

        - If your answer to Question 3a is no, then FDA must receive your product's ingredient listing by August 8, 2017.

- If your answer to Question 3 is no, FDA must receive your product's ingredient listing at least 90 days before the product is delivered for introduction into interstate commerce.
    - This applies to both (1) previously marketed products that were discontinued or withdrawn before August 8, 2016, and reintroduced after August 8, 2016, and (2) products marketed for the first time after August 8, 2016.

IMPORTANT NOTE: **Failure to provide ingredient listing information is a prohibited act. FDA would consider a tobacco product without an ingredient listing on file by the applicable compliance date misbranded and subject to FDA regulatory and enforcement action, including possible seizures, injunctions, and import refusals.**

WHAT INFORMATION MUST BE SUBMITTED?

WHAT INFORMATION IS REQUIRED TO BE SUBMITTED IN AN INGREDIENT LISTING?

You must provide the following information in your ingredient listing submission:[1]

- Manufacturer/Importer Identification

  - Identify role: Manufacturer or Importer
  - Name and title of the responsible person or agent making the submission (responsible official or agent authorized to represent the submitter)
  - Company name and address
  - Authorized agent's company name and address, if submitted by one
  - Name and address of U.S. Agent, if submitted by a foreign entity
  - Optional fields include a corporate email address, a Company Headquarters Data Universal Numbering System (DUNS) number, and a facility establishment identifier (FEI) number assigned to your establishment by FDA

  - NOTE FOR IMPORTERS: If you are submitting ingredient listings for finished products you import from more than one manufacturer, you must complete a separate submission for each foreign manufacturer of those products.

[1] This document generally describes the required and optional manual-entry fields in the eSubmitter software that industry may use to prepare ingredient listings. Note that both the information fields included and whether FDA has designated them as "required" or "optional" are not consistent across Form FDA 3742 and the two eSubmitter data entry vehicles (i.e., the manual-entry option and the spreadsheet template).

- Product Identification

  - Submit one ingredient list for each unique tobacco product. Tobacco products are unique when they "differ in any way other than packaging differences that do not affect product characteristics."

    - For example, each unique e-liquid formulation, flavor, nicotine concentration, and bottle size would be a distinct tobacco product that requires its own ingredient listing submission.

    - If your product is sold in different packaging configurations, but the packaging differences do not affect the product's characteristics, you should submit a single ingredient list for the product, noting the different packaging configurations.

  - Identify each product by brand and sub-brand, including the category of tobacco product (e.g., electronic nicotine delivery systems (ENDS)) and subcategory (e.g., closed e-cigarette, open e-cigarette, closed e-liquid, open e-liquid). Include additional identifiers (e.g., SKU numbers, UPCs, and catalog numbers) as needed to uniquely identify the product. You can identify more than one product on an ingredient listing when the same physical product is marketed under different brands or sub-brands.

- Ingredient Identification

  - Include (1) all ingredients added directly by, or at the direction of, the tobacco product manufacturer, (2) all ingredients known or intended to be formed through a chemical reaction during tobacco product manufacturing, (3) all ingredients known or intended to be added to packaging that will become incorporated into the consumed product, and (4) solvents or other ingredients that are added and subsequently removed during manufacturing.

  - NOTE: FDA recommends that you internally assign a unique ingredient number (IN#) for each ingredient. Each ingredient must be uniquely identified to distinguish it from similar or related materials.

  - ***For single chemical substances***, list the unique scientific name or code (e.g., FDA UNII Code, CAS Number, IUPAC Name). FDA also requests that you identify the quality of the ingredient (e.g., percent purity, published standard) (if any), any internal identification number used, the expected function of the ingredient in the final product (e.g.,

humectant, flavor), and any additional information on the ingredient; FDA has provided an Ingredient Function List (Appendix A of Form FDA 3742). Nicotine, PG, and VG would likely be considered single chemical substances.

- ***For complex purchased ingredients,*** such as flavorings, there are two categories:
  - If a complex purchased ingredient is made to your specifications (i.e., not available as a commodity but custom prepared for you to meet certain, ingredient-specific formulation specifications), then you must provide:
    - Manufacturer name,
    - Unique identifying name and/or number (e.g., catalog number or UPC) used by the manufacturer, and
    - For each ingredient that you specified be included by the manufacturer, the unique scientific name or code (e.g., FDA UNII Code, CAS Number, IUPAC Name).
  - If a complex purchased ingredient is not made to your specifications (e.g., purchased proprietary flavors for which you do not specify the use of particular ingredients, off-the-shelf components) then you must provide:
    - Manufacturer name, and
    - Unique identifying name and/or number used by the manufacturer (catalog number or UPC assigned by the seller).
    - NOTE: You need not list any sub-ingredients of a complex purchased ingredient not made to your specifications.
  - For both categories of complex purchased ingredients, FDA requests that you identify the quality of the ingredient (e.g., percent purity, published standard) (if any), any internal identifier used, the expected function of the ingredient in the final product (e.g., humectant, flavor), and any additional information on the ingredient; FDA has provided an Ingredient Function List (Appendix A of Form FDA 3742).

- NOTE: If you use a complex purchased ingredient provided by multiple suppliers interchangeably in a single tobacco product, you should report all alternative sources in your ingredient listing.

- Part to Which the Ingredient is Added (identify component of the tobacco product, e.g., e-liquid)

- Ingredient Quantity

  - Ingredients must be reported by quantity added by brand and sub-brand.

  - Ingredients should be reported as a single quantity whenever possible.

  - The quantities of ingredients must be provided in units of mass consistent across all products. For e-liquids, the quantity of an ingredient should be reported as the amount included per gram of the finished product.

  - Solvents or other ingredients added and subsequently removed during manufacturing should be identified, and the residual quantity should be reported. If the residual quantity is approximated as near zero, include an appropriate detection limit.

  - The quantities of ingredients may be calculated based on the added amounts and adjusted for known or intended losses and chemical reactions that occur during manufacturing.

  - The quantities reported may also be derived from laboratory testing.

HOW TO SUBMIT?

HOW DO I SUBMIT INGREDIENT INFORMATION?

Ingredient information can be submitted either electronically or by paper.

- Electronic Submission: FDA strongly encourages electronic submission. To submit electronically, follow these steps:

- If you have not previously submitted documents electronically to FDA, apply for a free account to submit electronic documents through either the CTP Portal or FDA's Electronic Submissions Gateway (ESG). Apply several weeks in advance of the date when you intend to submit your ingredient listing.
- Download the FDA eSubmitter tool and install it on your computer.
- Select "CTP Tobacco Product Ingredient Listing Submissions" within the eSubmitter program.
- Enter ingredient listing information directly into the software or use the software's template spreadsheets to import large quantities of data at the same time. When using eSubmitter, you will not need to prepare additional documents, including FDA Form 3742.
- Note that required responses are indicated by a blue dot located to the right of the question text. Other fields are considered optional.
- Upload the completed submission through the CTP Portal or ESG.
- Note that FDA will not accept ingredient listing submissions by e-mail.

➢ Paper Submission: To submit by paper, follow these steps:

- Complete FDA Form 3742[2] and
- Mail or have the submission delivered to:
  Food and Drug Administration
  Center for Tobacco Products
  Document Control Center
  Building 71, Room G335
  10903 New Hampshire Avenue
  Silver Spring, MD 20993-0002

[2] Note that FDA Form 3742 has not yet been updated to include the deemed product categories or FDA's new position that it will enforce this requirement for finished tobacco products only. The form likely will change at some point to include options for the newly deemed categories of products.

- Note that paper submissions sent to the Document Control Center by courier, delivery service, or physical mail will be considered timely only if received during delivery hours (8:00 am-4:00 pm) on or before the due date. If the due date falls on a weekend or holiday, the submission must be received on the prior business day during delivery hours.

IMPORTANT "DO NOT"

Given the scope of the current legal requirements and FDA's stated enforcement policies:

We do not recommend that any company submit an ingredient listing for products that are sold or distributed solely for further manufacturing (i.e., products that are not finished tobacco products).