

## DEEM THOSE LABELS! FDA COMPLIANT PACKAGING & ADVERTISING REFERENCE GUIDE

We've been getting lots of questions regarding the confusing or ambiguous rules and guidance provided by FDA in connection with the upcoming August 10, 2018 product labeling and packaging deadline. **Chris Howard**, Vice President, General Counsel and Chief Compliance Officer at E-Alternative Solutions, and a VTA Board Member, put together this reference guide to go along with the educational webinar we presented on April 5, 2018. We hope that this and the webinar addresses most of the questions that you have.

### *PACKAGING*

#### FDA NICOTINE WARNING

Required Language.

**“WARNING: This product contains nicotine.  
Nicotine is an addictive chemical.”**

Appearance and Placement. Warnings must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:

1. Be located in a conspicuous and prominent place on the two principal display panels of the package, and the warning area must comprise at least 30% of each of the principal display panels;
2. Be printed in at least 12-point font size and ensure that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;

### *In this Guidance*

**Packaging Restrictions**  
Page 1

**Advertising Restrictions**  
Page 3

**Deadlines**  
Page 3

3. Be printed in conspicuous and legible Helvetica bold or Arial bold type (or other sans serif fonts) and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the package;
4. Be capitalized and punctuated as indicated above; and
5. Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on the

principal display panel have the same orientation.

Small Packages. FDA provides specific guidance for small packages, see 21 CFR 1143(d) which provides that the warning may appear on the carton, outer container, wrapper or permanently affixed tag.

### **OTHER LABELING REQUIREMENTS (FDCA 903(A)(2))**

Tobacco products must bear a label containing:

1. The name and place of business of the product manufacturer, packer or distributor;
2. An accurate statement of the quantity in terms of weight, measure, or numerical count;
3. Percentage of domestic and foreign grown tobacco;
4. Statement: "Sale only allowed in the United States".

Domestic and Foreign Grown Tobacco. FDA recognized the difficulty in quantifying the amount of domestic and foreign grown tobacco that contributes to the nicotine in e-liquids, therefore, in draft guidance issued in January 2017 ("Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops") indicated that it would not enforce the provisions of section 903(a)(2)(c) at this time.

Statement of Quantity. An accurate statement of quantity can be accomplished in several ways. For example, e-liquid cartridges could be described as "1, 5ml Cartridge". A disposable cig-a-like product could be described as "1 [Insert Trade Name] device containing 2ml of e-liquid."

Origin Statement. The statement "Sale only allowed in the United States" is to be included on outer

packaging such as cartons and boxes as well as package labels.

Prominence. On packages all labeling must be prominent and in such terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use (903(a)(3)). This means that required language on labels should not be in such fine print to be unreadable to average consumers nor so similar to branding fonts to go unnoticed.

## **ADVERTISEMENTS**

Required Language. **"WARNING: This product contains nicotine. Nicotine is an addictive chemical."**

Appearance and Placement. Print and other advertisements with a visual component (including, for example, advertisements on signs, shelf-talkers, internet web pages, and electronic mail correspondence), must bear the required warning statement in the upper portion of the area of the advertisement within the trim area as follows:

1. Occupy at least 20% of the upper portion area of the advertisement;
2. Appear in at least 12-point font size and ensure that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;
3. Appear in conspicuous and legible Helvetica bold or Arial bold type (or other similar sans serif fonts) and in black text on a white background or white text on a black

- background in a manner that contrasts by typography, layout, or color, with all other material on the advertisement;
4. Be capitalized and punctuated as indicated above;
  5. Be centered in the warning area in which the text is required to appear and positioned such that the text of the required warning statement and the other textual information in the advertisement have the same orientation; and
  6. Be surrounded by a rectangular border that is the same color as the text of the required warning statement and that is not less than 3 millimeters or more than 4 millimeters.

## DEADLINES

The Tobacco Control Act (and implementing regulations) require that:

1. Manufacturers cannot manufacture products with non-compliant packages as of **August 10, 2018** (21 CFR 1143),
2. Manufacturers cannot distribute non-compliant packages as of **September 11, 2018** (21 CFR 1143),
3. Retailers cannot offer for sale, sell, distribute, or import products with non-compliant packages unless the retailer falls within the safe harbor (see below) as of **August 10, 2018**

- a. A retailer ... will not be in violation of this section for packaging that (i) Contains a health warning; (ii) Is supplied to the retailer by the tobacco product manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and trade Bureau (TTB) – issued license or permit, if applicable, and (iii) Is not altered by the retailer in a way that is material to the requirements of this section. 21 CFR 1143(a)(3)(ii),
4. Manufactures, importers, distributors and retailers who direct their own advertising must include the addictiveness warning as of **August 10, 2018** (21 CFR 1143), and
5. Products are misbranded if they do not include the FDCA 903(a)(2) required labeling as of **August 10, 2018**.