VAPOR TECHNOLOGY ASSOCIATION

VTA GUIDANCE

Labeling/Packaging Sell Through
August 9, 2018

# FDA LABELING & PACKAGING DEADLINE AND SELL-THROUGH RIGHTS OF DISTRIBUTORS & RETAILERS

This guidance document updates the prior detailed guidance on labeling and advertising that VTA published on April 5, 2018. We've received many questions about what the various dates mean, what do manufacturers and retailers do with product in their possession that have non-compliant labels, is there a sell-through period, and what must manufacturers or distributors or retailers do? We directly address the operation of the relevant compliance dates and the *rights of distributors and retailers* for selling products with non-compliant warning statements.

## NICOTINE ADDICTIVENESS WARNING

FDA regulations issued under the Tobacco Control Act require that packaging for ENDS products containing tobacco-derived nicotine must bear the FDA Nicotine Addictiveness Warning.

The regulations have an August 10, 2018, effective date (hereinafter, the "**effective date**").

Warning Statement. FDA requires that each package contain the following statement:

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

The statement must be formatted and placed on the package in accordance with FDA's regulation at 21 C.F.R. § 1143.3. (For more information, see our prior guidance on the subject.)

## KEY DATES

Per the regulations, the August 10, 2018, effective date is "with respect to the date of manufacture."

As of **August 10, 2018**, manufacturers may not **manufacture** products with non-compliant labels. Period.

As of **September 11, 2018**, manufacturers may not **introduce into commerce** products with non-compliant labels, even if that product was manufactured before August 10, 2018.

However, up and until September 10, 2018, manufacturers may continue to introduce into commerce non-compliant products manufactured before August 10, 2018. In short, manufacturers have only 30 days to ship any inventory of pre-August 10, non-compliant product.

For their part, distributors/wholesalers and retailers may continue to sell non-compliant product as set forth below.

# SELLING THROUGH NON-COMPLIANT PRODUCTS

VTA has recently received questions from wholesalers, distributors and retailers regarding whether FDA has provided additional insight regarding how non-compliant products should be handled. FDA has made it clear that distributors/wholesalers and retailers may continue to sell products *without* the Nicotine Addictiveness Warning after August 10, 2018, *if* such products were manufactured before the compliance date.

FDA explains these sell-through rights in several of its publications:

Guidance Documents. In its December 2016 revision of the *Small Entity Compliance Guide* FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements, FDA addressed distributors' and retailers' right to sell off noncompliant products in their inventory after August 10, 2018:

**"11. After the effective date for the health warnings, can distributors and retailers sell-off their remaining stock of covered tobacco products, cigarette tobacco, and RYO tobacco if the packaging does not does not comply with the new health warning requirements?**

Yes. Distributors and retailers may continue to sell and distribute the tobacco product packages after the effective date, but only if the products were manufactured before the effective date of the new required warning statement for covered tobacco products, cigarette tobacco and RYO tobacco." (See, Small Entity Compliance Guide, page 22.)

Also, in its June 2016 revision of its Guidance for Industry entitled Tobacco Retailer Training Programs, FDA responded to industry requests to acknowledge that, by operation of the regulation itself, retailers may continue to sell products manufactured before August 10, 2018, without compliant labels:

"...[R]etailers may continue to sell and distribute tobacco products with packaging that does not bear the required health warning statements after the effective date, but only if the products were manufactured before the effective date of the warning statement requirements."

(See, Tobacco Retailer Training Programs (Revised) Guidance for Industry, page 4, footnote 6.)

Deeming Regulation. In the preamble to the final deeming regulation, FDA confirmed that downstream businesses may import and distribute non-compliant packages of product manufactured prior to the effective date for the warning regulations in 21 C.F.R. part 1143:

"After the effective date, a distributor or retailer may not sell, offer to sell, distribute, or import for sale or distribution within the United States any such product the package of which does not comply with this regulation, *unless the covered tobacco product was manufactured prior to the effective date*." 81 Fed. Reg. 28,974, 28,977 (May 10, 2016) (emphasis added).

FDA Compliance Website. More recently, FDA also states the following on its internet-based guidance website: "FDA does not intend to enforce these … warning statement requirements for products that were manufactured before the effective date (August 10, 2018) of the new required warning statement for covered tobacco products, cigarette tobacco, and RYO tobacco." (See, Summary of Federal Rules for Tobacco Retailers, at Reference 1, Page Last Updated: 07/28/2018.) Note that FDA states that it does not "intend to" enforce the requirements for products manufactured before August 10, 2018, even though the regulation would not permit such enforcement in any event.)

## SAFE HARBOR FOR RETAILERS

In addition to having the ability to sell non-compliant products manufactured before the effective date, retailers may also qualify for a separate safe harbor enabling them to sell non-compliant products after the August 10, 2018 effective date. This safe harbor providing retailers with a right to sell such products is described as follows:

*"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."* (See, 21 C.F.R. § 1143.3(a)(3).)

## FINAL THOUGHTS

While certain other FDA guidance documents tend to confuse the issue somewhat, FDA has made clear that the regulation permits distributors and retailers to continue to sell-through, for an unlimited period of time, products in packaging that does not bear the required warning statement so long as the product was manufactured before August 10, 2018.

The obligation for suspending sales of pre-August 10 products in non-compliant packaging after September 10, 2018, **is on the manufacturer alone**.

Prudence suggests that distributors and retailers should reasonably avoid purchasing product with non-compliant packaging *from a manufacturer* after September 10, 2018. However, retailers may confidently (1) purchase *from distributors and wholesalers,* and (2) sell products, with non-compliant packaging, after September 10, 2018, until that product inventory is gone, provided the *products were manufactured before the effective date*.

Finally, while FDA has acknowledged that distributors and retailers may sell product manufactured before the effective date without compliant warnings, as good stewards of industry, distributors and retailers should consider seeking and maintaining evidence that non-compliant products purchased after August 10, 2018, were in fact manufactured before the effective date.