

## Smokeless Tobacco- Required Warning Statements

Since July 22, 2010, smokeless tobacco product packaging and advertising must bear ***one of the following*** required warning label statements, per section 3 of the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA), as amended by section 204 of the Tobacco Control Act, in accordance with an FDA approved warning plan:

- **WARNING:** This product can cause mouth cancer.
- **WARNING:** This product can cause gum disease and tooth loss.
- **WARNING:** This product is not a safe alternative to cigarettes.
- **WARNING:** Smokeless tobacco is addictive.

<https://www.fda.gov/TobaccoProducts/Labeling/Labeling/ucm2023662.htm#statements>

## Cigars- Required Warning Statements

As of August 10, 2018, all cigar packages that are manufactured, packaged, sold, offered for sale, distributed, or imported for sale or distribution within the United States must bear ***one of the following*** required warning statements, per 21 CFR § 1143.5(a)(1), on the package label:

- **WARNING:** Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- **WARNING:** Cigar smoking can cause lung cancer and heart disease.
- **WARNING:** Cigars are not a safe alternative to cigarettes.
- **WARNING:** Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- **WARNING:** Cigar use while pregnant can harm you and your baby.  
or  
**SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.\***
- **WARNING:** This product contains nicotine. Nicotine is an addictive chemical.

\*You may choose to display either one of the warning statements regarding reproductive health. FDA expects that providing this optional alternative will benefit entities bound by the Federal Trade Commission (FTC) consent decrees, and the statement is appropriate for the protection of public health.

<https://www.fda.gov/TobaccoProducts/Labeling/Labeling/ucm524442.htm>

## Cigarettes- Required Warning Statements

Any person who manufactures, packages, or imports for sale or distribution cigarettes within the United States must continue to comply with the requirements for cigarette health warnings under the Federal Cigarette Labeling and Advertising Act (FCLAA), as in effect before amendment by the Family Smoking Prevention and Tobacco Control Act.

15 U.S.C. §§ 1331-1340; 21 U.S.C. § 387c

§ 1333. Labeling; requirements; conspicuous statement

(a) Required warnings; packages; advertisements; billboards

(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, ***one of the following*** labels:

**SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.**

**SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.**

**SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.**

**SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.**

<https://www.ftc.gov/enforcement/statutes/federal-cigarette-labeling-advertising-act>

## **"Covered" Tobacco Product and Roll-Your-Own/Cigarette Tobacco Labeling and Warning Statement Requirements**

Beginning August 10, 2018, you cannot manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States roll-your-own, cigarette tobacco, or "covered tobacco products" without the required warning label statement on the tobacco product package, per 21 CFR § 1143.3(a)(1). (Cigar required warnings are described under 21 CFR § 1143.5.)

For the following products, including components and parts, that are sealed in final packaging intended for consumer use and are made or derived from tobacco, package labels and advertisements must bear the nicotine addictiveness warning statement:

- hookah
- pipe tobacco
- vaporizers, e-cigarettes, and other electronic nicotine delivery systems (ENDS)
- dissolvables
- gels
- roll-your-own and cigarette tobacco

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

### **Zero-Nicotine: Self-certification and Alternative Required Warning Statement**

If the product does not contain nicotine and is made or derived from tobacco, the tobacco product manufacturer may display the alternative warning statement, instead of the nicotine addictiveness warning statement.

The alternative warning statement, under 21 CFR § 1143.3(c), for applicable package labels and advertisements reads:

**"This product is made from tobacco."**

Products that are **not** made or derived from tobacco do not meet the definition of "covered tobacco product" and are not required to carry any of the required warnings or to submit a self-certification.

<https://www.fda.gov/TobaccoProducts/Labeling/Labeling/ucm524470.htm>