

Guidance for Industry and FDA Staff

Use of “Light,” “Mild,” “Low,” or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products

June 2010

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-287-1373 or refer to <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products**

Preface

Public Comment

Written comments and suggestions may be submitted at any time for agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Alternatively, electronic comments may be submitted to <http://www.regulations.gov>. Please identify your comments with the docket number listed in the notice of availability that publishes in the *Federal Register* announcing the availability of this guidance document. Comments may not be acted upon by the agency until the document is next revised or updated.

Additional Copies

Additional copies are available from: Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850, (Tel) 1-877-287-1373, <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

This guidance provides information in response to questions related to the use of “light,” “mild,” “low,” or similar descriptors in the label, labeling, or advertising of tobacco products, as provided in section 911(b) of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Family Smoking Prevention and Tobacco Control Act (Public Law 111-31).

I. Background

Section 911(b)(2)(A)(ii) of the act prohibits the use of the descriptors “light,” “mild,” or “low,” or similar descriptors in tobacco product label, labeling, or advertising unless an FDA order is in effect under section 911(g) with respect to such product. In prohibiting the use of “light,” “mild,” and “low,” Congress found that many smokers mistakenly believe that cigarettes marketed with these descriptors cause fewer health problems than other cigarettes, and that those mistaken beliefs can reduce the motivation to quit smoking. Studies have demonstrated that there has been no reduction in health risk from such products, and such products may actually increase the risk of tobacco use. Congress

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determined that prohibiting the use of “light,” “mild,” and “low,” and similar descriptors was necessary to protect the public health and important to ensuring that tobacco product label, labeling, and advertising are truthful and not misleading.

II. Questions and Answers

1. What happens on June 22, 2010?

As of June 22, 2010, manufacturers may not manufacture for sale or distribution any tobacco products for which the label, labeling, or advertising contains the descriptors “light,” “low,” or “mild,” or any similar descriptor, without an FDA order in effect under section 911(g) of the act (section 911(b)(3) of the act). However, manufacturers may continue to introduce into domestic commerce existing inventory of such products for an additional 30 days (section 911(b)(3) of the act).

2. What happens on July 22, 2010?

As of July 22, 2010, manufacturers, including importers of finished tobacco products, may not introduce into the domestic commerce of the United States any tobacco product for which the label, labeling, or advertising contains the descriptors “light,” “low,” or “mild,” or any similar descriptor, irrespective of the date of manufacture, without an FDA order in effect under section 911(g) of the act (section 911(b)(3) of the act).

3. How will the prohibition against the use of these descriptors be enforced?

As of July 22, 2010, manufacturers, including importers of finished tobacco products, who introduce into domestic commerce any tobacco product for which the label, labeling, or advertising contains the descriptors “light,” “low,” or “mild,” or any similar descriptor, irrespective of the date of manufacture, will be in violation of the act unless an FDA order is in effect under section 911(g) with respect to such product (section 911(b)(3) of the act). Under section 902(8) of the act, a tobacco product shall be deemed to be adulterated if it is in violation of section 911 of the act.

Under section 304 of the act, adulterated tobacco products that are sold or held for sale in the United States are subject to seizure, and under section 801(a) of the act, adulterated tobacco products that are imported into the United States are subject to refusal of admission. In addition, FDA has the authority to initiate, among other actions, injunction actions, civil money penalties, and/or criminal prosecution to address violations of the act (sections 302 and 303 of the act).

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- 4. May distributors, wholesalers, and retailers distribute or sell tobacco products in their possession for which the label, labeling, or advertising contains the descriptors “light,” “low,” or “mild,” or any similar descriptor after July 22, 2010?**

Yes, if the products were manufactured before June 22, 2010, and introduced into domestic commerce by the manufacturer, which includes an importer of finished tobacco products, before July 22, 2010.