

## FDA Confirms Sell Through on Products Bearing Old Descriptors After Repeated Requests by AWMA

Memo - June 7, 2010

To: AWMA Members

From: Scott Ramminger, President

I'm very pleased to report that after repeated meetings with and letters to top FDA officials we have finally received guidance from the agency that FDA will in fact be allowing an unlimited sell through (downstream of the manufacturer) of tobacco products bearing the old descriptors ("Light," "Ultra Light," etc.).

AWMA voiced concerns about FDA's lack of clarity on the sell-through at our May 13th "AWMA Day on the Hill" meeting with the Chief of Compliance for FDA. Ann Simoneau, who - at the time - cast doubt on whether a sell through would be allowed.. We followed up with a letter to Simoneau and a meeting with FDA Ombudsman Lester Weinstein to reiterate our concerns.

The guidance document, issued over the weekend, notes specifically that the agency has decided to allow distributors to sell through product bearing the old descriptors manufactured before the June 22nd manufacturing cutoff. Manufacturers have then have until July 22nd to ship product with the old descriptors manufactured before the June deadline has passed.

I am also pleased to report that we seemed to have formed a viable working relationship with the top FDA officials who are forging the implementation of the regulation. Ms. Simoneau took the time to personally notify us of the FDA decision.

AWMA will continue to work vigorously on behalf of our distributor members to ensure that our concerns are understood as this new tobacco law is implemented by the FDA. And, we will continue to keep our members apprised of new developments as this issue goes forward.

### The Full Text of FDA's Guidance

#### *Guidance for Industry and FDA Staff: Use of "Light," "Mild," "Low," or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products*

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 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).

**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.