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Guidance for Industry and FDA Staff

Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco

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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 (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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

Guidance for Industry and FDA Staff

Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco

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 is intended to provide information related to certain provisions of the regulations restricting the sale and distribution of cigarettes and smokeless tobacco. See 75 Federal Register 13225 (March 19, 2010). These regulations are effective June 22, 2010.[1] More specifically, this guidance provides clarifying information related to FDA's enforcement policy concerning 21 CFR sections 1140.16(a) and 1140.32(a) of the final rule.

Section 1140.16(a).

Under this section of the final rule, manufacturers may not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product unless the trade or brand name was on both the tobacco product and a nontobacco product sold in the United States on January 1, 1995. FDA is aware of concerns regarding this provision and is considering what changes, if any, would be appropriate to address those concerns.[2] While FDA has this issue under consideration, it intends to exercise its enforcement discretion concerning 21 CFR 1140.16(a) not to

[1] The final rule published March 19, 2010, in the Federal Register, and is available at the Center for Tobacco Product's website: http://www.fda.gov/tobaccoproducts.

[2] Under section 102(a)(3)-(4) of Family Smoking Prevention and Tobacco Control Act (21 USC 387a-1(a)(3)-(4)), FDA may amend the final rule after issuing a proposed rule for notice and comment.

commence enforcement actions under this provision for the duration of its consideration where:

(1) The trade or brand name of the cigarettes or smokeless tobacco product was registered, or the product was marketed, in the United States on or before June 22, 2009; or

(2) The first marketing or registration in the United States of the tobacco product occurs *before* the first marketing or registration in the United States of the non-tobacco product bearing the same name; provided, however, that the tobacco and non-tobacco product are not owned, manufactured, or distributed by the same, related, or affiliated entities (including as a licensee).

Section 1140.32(a).

Under this section of the final rule, manufacturers, distributors, and retailers must use only black text on a white background for labeling or advertising (with certain exceptions). The United States District Court for the Western District of Kentucky recently issued an order permanently enjoining FDA from enforcing section 21 CFR 1140.32(a) (formerly section 897.32(a) of the 1996 final rule) (*Commonwealth Brands, Inc. v. United States*, No. 1:09-CV-117-M (W.D. Ky. Jan. 4, 2010)). The injunction prevents enforcement of this provision against the parties to the case in any jurisdiction in the United States. On March 8, 2010, the government filed an appeal from that order.

As required by section 102 of the Tobacco Control Act, the effective date for 21 CFR 1140.32(a) is June 22, 2010. At this time, however, in light of the court's order in *Commonwealth Brands*, FDA intends to exercise its enforcement discretion concerning 21 CFR 1140.32(a) not to commence enforcement actions under this provision during the pendency of the litigation irrespective of whether the entity is a party to the pending lawsuit or located in the Western District of Kentucky.