DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
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Due to ongoing litigation, the implementation of FDA's final rule entitled "Required Warnings for Cigarette Packages and Advertisements" ("June 2011 Rule") -- which requires larger, more prominent health warnings on all cigarette packaging and advertisements in the United States and was scheduled to become effective in September 2012 -- is uncertain. (The case is *R.J. Reynolds Tobacco Co. v. U.S. Food and Drug Administration*, No. 11-1482 (D.D.C.), on appeal, Nos. 11-5332, 12-5063 (D.C. Cir.).)

Anyone who manufactures, packages, or imports for sale or distribution cigarettes within the United States, and any manufacturer or importer who advertises or causes to be advertised cigarettes within the United States, must continue to comply with the requirements for cigarette health warnings under the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1340 ("FCLAA"), as in effect before amendment by the Family Smoking Prevention and Tobacco Control Act. Pending further notice, the Federal Trade Commission (FTC) will continue to have responsibility for the review and approval of cigarette warning plans under the existing FCLAA requirements, and all questions regarding the submission, review, or approval of such plans should be addressed to FTC.

Likewise, at this time, FDA will not be soliciting or reviewing cigarette warning plans. In the future, FDA may notify the public that it is requesting and accepting the submission of cigarette warning plans in advance of the effective implementation date for the June 2011 Rule. Companies that manufacture, package, sell, offer to sell, distribute or import for sale or distribution cigarettes within the United States should closely follow FDA and FTC for future updates concerning the submission, review, and approval of cigarette warning plans.

In addition, because of uncertainties caused by ongoing litigation, those who manufacture, package, sell, offer to sell, distribute or import for sale or distribution cigarettes* within the United States will not be expected to comply with Section 903(a)(2) of the Federal Food Drug and Cosmetic Act with respect to cigarette packaging and labels until further notice from FDA. This means that, until such further notice, these entities will not be expected to include the following statements on cigarette labels or packaging:

• the name and place of business of the tobacco product manufacturer, packer, or distributor (903(a)(2)(A));

• an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count (903(a)(2)(B));

• an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco (903(a)(2)(C)); and

• where applicable, the statement: "sale only allowed in the United States" (903(a)(2)(D) and 920(a)(1)).

* The definition of "cigarette" as applicable to section 903(a)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), in pertinent part, "includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco." Section 900(3) of the FDCA. Accordingly, FDA is clarifying that because of uncertainties caused by ongoing litigation, those who manufacture, package, sell, offer to sell, distribute or import for sale or distribution roll-your-own tobacco (as defined in section 900(15) of the FDCA) within the United States will not be expected to comply with Section 903(a)(2), as set forth above, until further notice.

Updated: 7/25/2012