DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA-2014-N-0189]

RIN 0910-AG38

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as

Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale
and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to deem products meeting the statutory definition of "tobacco product," except accessories of the newly deemed tobacco products, to be subject to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The Tobacco Control Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. With this final rule, FDA is extending the Agency's "tobacco product" authorities in chapter IX of the FD&C Act to all other categories of products that meet the statutory definition of "tobacco product" in the FD&C Act, except accessories of such newly deemed tobacco products. This final rule also prohibits the sale of "covered tobacco products" to individuals under the age of 18 and requires the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements. FDA is taking this action to reduce the death and disease from tobacco products.

In accordance with section 5 of the Tobacco Control Act, we consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.



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