



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1142

[Docket No. FDA-2012-N-1032]

Smokeless Tobacco Product Warning Statements; Request for Comments and Scientific Evidence

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to obtain comments, supported by scientific evidence, regarding what changes to the smokeless tobacco product warnings, if any, would promote greater public understanding of the risks associated with the use of smokeless tobacco products.

DATES: Submit electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Public Law 111-31) (Tobacco Control Act) into law. The Tobacco Control Act grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors.

Section 204 of the Tobacco Control Act amended section 3 of the Comprehensive Smokeless Tobacco Health Education Act (Smokeless Tobacco Act) (15 U.S.C. 4402) to prescribe new requirements for health warnings that must appear on smokeless tobacco product packages and advertising. The Smokeless Tobacco Act (15 U.S.C. 4402(a)(1) and (b)(1)), requires that smokeless tobacco product packages and advertising must bear one of four required warning statements. The four required warning statements are:

“WARNING: This product can cause mouth cancer.”

“WARNING: This product can cause gum disease and tooth loss.”

“WARNING: This product is not a safe alternative to cigarettes.”

“WARNING: Smokeless tobacco is addictive.” (15 U.S.C. 4402(a)(1))

One of the four required warning statements must be located on each of the two principal display panels of the package and comprise at least 30 percent of each such display panel (15 U.S.C. 4402(a)(2)(A)). The Smokeless Tobacco Act (15 U.S.C. 4402(a)(2) and (b)(2)), also sets

forth requirements for the placement, type, size, and color of warnings on packaging and advertisements, respectively.

Section 205(a) of the Tobacco Control Act further amended section 3 of the Smokeless Tobacco Act to give FDA the authority to “adjust the format, type size and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act” through rulemaking conducted under the Administrative Procedures Act (5 U.S.C. 552, *et seq.*) if FDA “finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products” (15 U.S.C. 4402(d)).

II. Request for Scientific Evidence and Information

We are interested in comments, supported by scientific evidence, regarding what changes, if any, to the smokeless tobacco product warnings would promote greater public understanding of the risks associated with the use of smokeless tobacco products. The “public” includes both tobacco users and nonusers (i.e., never users and former users). Comments and supporting evidence should address how any changes in the warnings would affect both users’ and nonusers’ understanding of the risks associated with the use of smokeless tobacco products.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received

comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: January 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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