[Billing Code: 6750-01S]

FEDERAL TRADE COMMISSION

Proposal to Rescind FTC Guidance Concerning the Current Cigarette Test Method

AGENCY: Federal Trade Commission

ACTION: Notice

its proposal.

SUMMARY: The Federal Trade Commission ("FTC" or "Commission") is proposing to rescind its guidance that it is generally not a violation of the FTC Act to make factual statements of the tar and nicotine yields of cigarettes when statements of such yields are supported by testing conducted pursuant to the Cambridge Filter Method, also frequently referred to as "the FTC Test Method." If it withdraws this guidance, advertisers should not use terms such as "per FTC Method" or other phrases that state or imply FTC endorsement or approval of the Cambridge Filter Method or other machine-based test methods. The Commission seeks public comments on

DATES: Comments must be submitted on or before August 12, 2008.

ADDRESSES: Interested parties are invited to submit comments. Comments should refer to "Cigarette Test Method, [P944509]" to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered, with two complete copies, to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex L), 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Because paper mail in the Washington area and at the Commission is subject to delay, please consider submitting your comments in electronic form, as described below. However, if the comment contains any material for which confidential treatment is

requested, it must be filed in paper form, and the first page of the document must be clearly labeled "Confidential."

Comments filed in electronic form should be submitted by following the instructions on the web-based form at https://secure.commentworks.com/ftc-CigaretteTestMethod. To ensure that the Commission considers an electronic comment, you must file it on the web-based form at the https://secure.commentworks.com/ftc-CigaretteTestMethod weblink. If this Notice appears at www.regulations.gov, you may also file an electronic comment through that web site. The Commission will consider all comments that regulations.gov forwards to it.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC web site, to the extent practicable, at www.ftc.gov. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at https://www.ftc.gov/ftc/privacy/htm.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to Rosemary Rosso, Senior Attorney, Division of Advertising Practices, Bureau of

Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. See Commission Rule 4.9(c), 16 CFR 4.9(c).

Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580, (202) 326-2174.

supplementary information: Cigarette yields for tar, nicotine, and carbon monoxide are currently measured by the Cambridge Filter Method, which has been commonly referred to as "the FTC Method." For some time, the Commission has been concerned that the machine-measured yields determined by the Cambridge Filter Method may be misleading to individual consumers who rely on the yields as indicators of the amount of tar, nicotine, and carbon monoxide they actually will get from smoking a particular cigarette. In fact, the current yields tend to be relatively poor indicators of tar, nicotine, and carbon monoxide exposure, and do not provide a good basis for comparison among cigarettes. Accordingly, the Commission proposes to withdraw its guidance, announced in 1966, indicating that factual statements of tar and nicotine yields based on the Cambridge Filter Method generally will not violate the FTC Act. If the Commission withdraws this guidance, advertisers should not use terms such as "per FTC Method" or other phrases that state or imply FTC endorsement or approval of the Cambridge Filter Method or other machine-based test methods. The Commission invites public comment on its proposal.

I. BACKGROUND

On March 25, 1966, the Commission informed the major cigarette manufacturers that factual statements of the tar and nicotine content of the mainstream smoke of cigarettes would not be in violation of legal provisions administered by the FTC:

so long as: (1) no collateral representations (other than factual statements of tar and nicotine content of cigarettes offered for sale to the public) are made, expressly or by implication, as to reduction

or elimination of health hazards, and (2) the statement of tar and nicotine content is supported by adequate records of tests conducted in accordance with the Cambridge Filter Method.²

Importantly, the 1966 guidance only addresses simple factual statements of tar and nicotine yields. It does not apply to other conduct or express or implied representations, even if they concern tar and nicotine yields. Thus, deceptive claims about tar and nicotine yields or health risks are still subject to the full force of the Commission's jurisdiction. *See, e.g., FTC v. Brown & Williamson Tobacco Corp.*, 778 F. 2d 35 (D.C. Cir. 1985); *American Tobacco Co.*, 119 F.T.C. 3 (1995). Moreover, the Commission's 1966 guidance does not *require* companies to state the tar and nicotine yields of their cigarettes in their advertisements or on product labels. Rather, it sets forth the type of substantiation the Commission would deem adequate to support statements of tar and nicotine yields *if* cigarette companies choose to make such statements.

From the outset, cigarette testing under the Cambridge Filter Method was intended to produce uniform, standardized data about the tar and nicotine yields of mainstream cigarette smoke, *not* to replicate actual human smoking. Because no known test could accurately replicate human smoking, the FTC believed that the most important objective was to ensure that cigarette companies could present tar and nicotine information to the public based on a standardized method that would allow comparisons among cigarettes. In 1966, most public health officials believed that reducing the amount of "tar" in a cigarette could reduce a smoker's risk of lung

News Release of the Federal Trade Commission (Mar. 25, 1966) (reciting the text of identical letters sent to the major cigarette manufacturers and the Administrator of The Cigarette Advertising Code, Inc.). The Cambridge Filter Method determines the relative yields of individual cigarettes by "smoking" them in a standardized fashion, according to a predetermined protocol, on a machine. The machine is calibrated to take one puff of 2-seconds duration and 35 ml. volume every minute, and to smoke the cigarettes to a specified length.

cancer. Therefore, it was thought that giving consumers uniform and standardized information about the tar and nicotine yields of cigarettes would help smokers make informed decisions about the cigarettes they smoked.³

During the 40 years since the Commission announced this guidance, machine-measured tar and nicotine yields of cigarettes have decreased dramatically. In 1968, for example, only 2% of all cigarettes had machine-measured yields of 15 mg. or less. Today, over 85% of all cigarettes sold have machine-measured yields of 15 mg. or less.

Despite these dramatic decreases in machine-measured yields, the Commission has been concerned for some time that the current test method may be misleading to individual consumers who rely on the ratings it produces as indicators of the amount of tar and nicotine they actually will get from their cigarettes, and who use this information as a basis for comparison when choosing which cigarettes they smoke. In fact, the current yields tend to be relatively poor predictors of tar and nicotine exposure. This is primarily due to smoker compensation *i.e.*, the tendency of smokers of lower-rated cigarettes to take bigger, deeper, or more frequent puffs, or to otherwise alter their smoking behavior in order to obtain the dosage of nicotine they need. Such compensatory behavior in the way people smoke and changes in cigarette design that facilitate compensation can have significant effects on the amount of tar, nicotine, and carbon monoxide one gets from any particular cigarette.

Concerns about the machine-based Cambridge Filter Method became a substantial issue in the 1990s because of changes in modern cigarette design and due to a better understanding of the

When the test method was adopted, the public health community believed that "[t]he preponderance of scientific information strongly suggests that the lower the tar and nicotine content of cigarette smoke, the less harmful would be the effect." U.S. Dept. of Health and Human Services, *The Health Consequences of Smoking: The Changing Cigarette* 1 (1981) (quoting a 1966 Public Health Service statement).

To address these concerns, in 1994, the Commission, along with Congressman Henry Waxman, asked the National Cancer Institute ("NCI") to convene a consensus conference to address cigarette testing issues. That conference took place in December 1994. *Smoking and Tobacco Control Monograph 7: The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes: Report of the NCI Expert Committee*, National Institutes of Health, National Cancer Institute (1996).

In 1997, the Commission published a Federal Register Notice proposing certain changes to the test method in accordance with recommendations from the NCI consensus conference. 42 Fed. Reg. 48,158 (Sept. 12, 1997). In response, the cigarette companies argued in favor of retaining the existing test method. Public health agencies asked the Commission to postpone its proposed modifications until a broader review of unresolved scientific issues surrounding the system could be addressed.

In 1998, the Commission responded to the public health agencies' concerns by formally requesting that the Department of Health and Human Services ("DHHS") conduct a review of the FTC's cigarette test method. Letter from Donald S. Clark, Secretary, Federal Trade Commission to the Honorable Donna E. Shalala, Secretary, Department of Health and Human Services (Nov. 19, 1998). In particular, the Commission asked the DHHS to provide recommendations as to whether the testing system should be continued, and, if it should be continued, what specific changes should be made in order to correct the limitations previously identified by the NCI and other public health officials.

The DHHS provided its initial response to the FTC in an NCI Report concerning the public health effects of low tar cigarettes. *Smoking and Tobacco Control Monograph 13: Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, National Institutes of Health, National Cancer Institute (2001) ("Monograph 13"). The national panel of scientific experts assembled for the review concluded that the existing scientific evidence, including patterns of mortality from smoking-caused diseases, does not indicate a benefit to public health from changes in cigarette design and manufacturing over the past 50 years. Monograph 13 at 10. Monograph 13 also concluded that measurements of tar and nicotine as measured by the Cambridge Filter Method do not offer meaningful information to consumers. *Id.*

When it announced the release of Monograph 13, the NCI noted the FTC's previous request, and indicated that it would work with its sister science-based agencies at DHHS to determine what changes needed to be made to the testing method. National Cancer Institute, "Low-Tar Cigarettes: Evidence Does Not Indicate a Benefit to Public Health," *News from the NCI* (Nov. 27, 2001). The FTC understands that representatives from agencies within DHHS are continuing to look into these issues.

In light of its concerns, the Commission for more than a decade has recommended that Congress grant authority over cigarette testing to one of the federal government's science-based

Today, the consensus of the federal health agencies and the scientific community is that machine-based measurements of tar and nicotine yields using the Cambridge Filter Method "do not offer smokers meaningful information on the amount of tar and nicotine they will receive from a cigarette, or on the relative amounts of tar and nicotine exposure they are likely to receive from smoking different brands of cigarettes."

II. PROPOSAL TO RESCIND COMMISSION GUIDANCE CONCERNING FACTUAL STATEMENTS OF TAR AND NICOTINE YIELDS

The Commission proposes to rescind its guidance that generally permits factual statements about the tar and nicotine yields of a cigarette when such statements are supported by the Cambridge Filter Method.⁶ If it rescinds its guidance, advertisers should not use terms such as "per FTC Method" or other phrases that state or imply FTC endorsement or approval of the Cambridge Filter Method or other machine-based test methods.

public health agencies. *See, e.g.*, Prepared Statement of the Federal Trade Commission Before the Committee on Energy, Commerce, and Transportation, United States Senate (Nov. 13, 2007).

Testimony of Cathy Backinger, Ph.D., Acting Chief, Tobacco Control Research Branch, National Cancer Institute, presented before the Committee on Science, Commerce and Transportation, U.S. Senate (Nov. 13, 2007). *See also* Testimony of Jonathan M. Samet, M.D., M.S., Professor and Chair, Dept. of Epidemiology, Johns Hopkins Bloomberg School of Public Health, presented before the Committee on Science, Commerce and Transportation, U.S. Senate (Nov. 13, 2007); *Smoking and Tobacco Control Monograph 13: Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, National Institutes of Health, National Cancer Institute (2001).

Cigarette manufacturers have adopted descriptive terms such as "light" and "ultra low" apparently based on ranges of machine-measured tar yields. The Commission has not defined those terms, nor provided guidance or authorization as to the use of descriptors. Because there is no Commission enforcement policy with respect to the use of descriptors, this proposal does not address the use of descriptors.

A. Tar and Nicotine Statements Based on Cambridge Test Method

Given the serious limitations of the existing test method, the Commission's rationale for its 1966 guidance generally permitting factual tar and nicotine statements based on this methodology no longer appears valid. The Commission is concerned that statements based on the Cambridge Filter Method may be confusing or misleading to consumers who believe they will get proportionately less of the harmful substances from cigarette smoke by smoking relatively lower-yield cigarettes than from higher-yield cigarettes. Thus, the Commission proposes to rescind its guidance that generally permits claims based upon a single standardized machine-based test method the Cambridge Filter Method. Upon withdrawal of this guidance, factual statements about tar and nicotine yields would be evaluated the same as any other advertising or marketing claims subject to the Commission's jurisdiction: the statements could be made as long as they were truthful, non-misleading, and adequately substantiated.

B. Claims Stating or Implying FTC Endorsement or Approval

Additionally, the Commission believes it should not permit claims that consumers are likely to interpret as FTC approval, ownership, or endorsement of the Cambridge Filter Method. Thus, if the Commission withdraws the guidance, advertisers should not use terms such as "per FTC Method" or other phrases that state or imply FTC approval, ownership, or endorsement of the Cambridge Filter Method or other machine-based test methods.

III. REQUEST FOR COMMENTS AND RESPONSES TO SPECIFIC QUESTIONS

The Commission is seeking comment on the following specific questions and on any other issues relevant to the policies stated above in this Notice:

- Should the Commission rescind its guidance that generally permits factual statements about tar and nicotine yields when such statements are based on a single standardized test method the Cambridge Filter Method?
- What effects, if any, would the Commission's proposal likely have on consumers' purchases of cigarettes and/or their smoking behavior? Will these changes be likely to affect smoking intensity, brand choice, and/or the decision whether to quit smoking, and if so, how? How else would the proposal likely affect consumers?
 By direction of the Commission.

Donald S. Clark Secretary