

experienced a time lag between the time they file a request with the Commission and when the request is deemed submitted for the purpose of beginning the 60-day clock? How can the Commission improve on rendering advisory opinions promptly?

What else can the Commission do to improve the advisory opinion process?

#### B. Policy Statements and Other Guidelines

In recent years the Commission has issued a number of policy statements, which are available on the Commission's Web site at <http://www.fec.gov/law/policy.shtml>. Have these statements helped increase the transparency of the Commission's practices and procedures? How can the transparency of the Commission's practices and procedures be improved? Are there substantive or procedural flaws in any of these policy statements that the Commission should address or revise? Should any of these policy statements be embodied in regulations to provide better clarity and access to the public? Are there additional policy statements that the Commission should consider issuing? If so, what Commission practices and procedures should be addressed in the policy statements? Should policy statements, directives and guidelines be placed on the Web site?

What other policy statements could the Commission issue that would be helpful to the public?

#### IV. Other Issues

As noted above, the Commission welcomes comments on other issues relevant to these enforcement policies and procedures, including any comments concerning how the FEC might increase the fairness, substantive and procedural due process, efficiency and effectiveness of the Commission.

On behalf of the Commission.

Dated: December 2, 2008.

**Donald F. McGahn II,**

*Chairman, Federal Election Commission.*

[FR Doc. E8-28896 Filed 12-5-08; 8:45 am]

BILLING CODE 6715-01-P

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes

and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at [www.ffiec.gov/nic/](http://www.ffiec.gov/nic/).

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 2, 2009.

**A. Federal Reserve Bank of San Francisco** (Kenneth Binning, Vice President, Applications and Enforcement) 101 Market Street, San Francisco, California 94105-1579:

1. *Carpenter Fund Manager GP LLC; Carpenter Community Bancfund-A, L.P.; Carpenter Fund Management Company, LLC; Carpenter Community Bancfund, L.P.; Carpenter Community Bancfund CA, L.P.; SCJ, Inc.; CCFW, Inc. (dba Carpenter & Company)*, all of Irvine, California, to acquire CG Holdings, Inc., Wilmington, Delaware, and thereby indirectly acquire up to 80 percent of the voting shares of California General Bank, N.A. (in organization), Pasadena, California.

In connection with this application, CG Holdings, Inc., Wilmington, Delaware, has also applied to become a bank holding company by acquiring up to 80 percent of the voting shares of California General Bank, N.A. (in organization), Pasadena, California.

Board of Governors of the Federal Reserve System, December 3, 2008.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. E8-28933 Filed 12-5-08; 8:45 am]

BILLING CODE 6210-01-S

## FEDERAL TRADE COMMISSION

### Rescission of FTC Guidance Concerning the Cambridge Filter Method

**AGENCY:** Federal Trade Commission

**ACTION:** Notice

**SUMMARY:** The Federal Trade Commission ("FTC" or "Commission") has rescinded its 1966 guidance providing 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 Method." In addition, 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.

**DATES:** Except as specified in this notice, the Commission's rescission of the guidance is effective on November 26, 2008.

**ADDRESSES:** Requests for copies of this notice should be sent to the Consumer Response Center, Room 130, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580. The notice is also available on the Internet at the Commission's web site, <http://www.ftc.gov>.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be addressed to Rosemary Rosso, Senior Attorney, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580, (202) 326-2174.

**SUPPLEMENTARY INFORMATION:** Cigarette yields for tar, nicotine, and carbon monoxide are typically measured by the Cambridge Filter Method, which commonly has been referred to as "the FTC Method." On July 14, 2008, the Commission published a **Federal Register** notice seeking comment on a proposal to rescind guidance the Commission issued in 1966, which stated that it generally is 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. 73 Fed. Reg. 40350 (July 14, 2008). The Notice sought comment concerning the Commission's proposal, and the likely effects of rescission of the FTC guidance. On July 30, the Commission extended the comment

period until September 12, 2008. 73 Fed. Reg. 44268 (July 30, 2008).

## 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.<sup>1</sup>

Importantly, the 1966 guidance only addressed simple factual statements of tar and nicotine yields. It did not apply to other conduct or express or implied representations, even if they concerned tar and nicotine yields. Thus, deceptive claims about tar and nicotine yields or health risks continued to be 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 did not require companies to state the tar and nicotine yields of their cigarettes in their advertisements or on product labels. Rather, it set forth the type of substantiation the Commission would deem adequate to support statements of tar and nicotine yields if cigarette companies chose 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 test known at the time 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 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.<sup>2</sup>

Despite dramatic decreases in machine-measured tar and nicotine yields since then, 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, or 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.

Concerns about the machine-based Cambridge Filter Method became a substantially greater issue in the 1990s because of changes in modern cigarette design and due to a better understanding of the nature and effects of compensatory smoking behavior.<sup>3</sup>

<sup>2</sup> 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).

<sup>3</sup> 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

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."<sup>4</sup>

Given the serious limitations of the existing test method, the Commission published a **Federal Register Notice** seeking comment on a proposal to rescind its guidance providing that factual statements supported by testing conducted pursuant to the Cambridge Filter Method generally would not violate the FTC Act.

## II. COMMENTS RECEIVED IN RESPONSE TO COMMISSION'S NOTICE

The Commission received 36 comments in response to its **Federal Register Notice**.<sup>5</sup> Of those, 27 commenters supported the proposal to rescind the 1966 guidance, seven comments opposed the proposal, and two comments neither supported nor opposed the specific proposal to rescind the 1966 guidance.<sup>6</sup> The comments are discussed below.

Human Services (Nov. 19, 1998). 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.

<sup>4</sup> 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); Monograph 13.

<sup>5</sup> The comments are cited in this notice by reference to the name of the commenter. The comments are available on the Internet at the Commission's web site, <http://www.ftc.gov>. The comments also are on the public record and are available for public inspection by contacting the Consumer Response Center, 600 Pennsylvania Avenue, NW, Washington, DC 20580 from 9 a.m. to 5 p.m. Monday through Friday, except federal holidays.

<sup>6</sup> One of these comments, from a church organization, indicated the group's general concern that any tobacco use is harmful. In addition, an individual expressed the view that the Commission was complicit in deceptions by cigarette companies.

<sup>1</sup> 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 pre-determined 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.

### A. Comments Supporting the Proposal

Comments supporting the Commission's proposal to rescind its 1966 guidance came from public health and tobacco advocacy organizations, an international health organization, a municipal health department, academic and health professionals, individuals, and Members of the United States Senate.<sup>7</sup>

#### 1. Basis for Support

One commenter, an official at the American Cancer Society, stated that the guidance should be rescinded because it has not served its purpose of informing consumers about brands that confer less risk of tobacco-related harm.<sup>8</sup> Several commenters indicated their support for the proposal because the tar and nicotine yields derived through the Cambridge Filter Method do not provide meaningful information about the relative health risks among cigarette brands.<sup>9</sup> Other commenters stated that machine-based yields do not provide meaningful information to consumers about the amount of tar and nicotine actually inhaled by smokers or the differences in exposure they would receive when switching brands of cigarettes.<sup>10</sup> Some of these commenters cited research showing that there is no meaningful difference in a smoker's exposure to tar and nicotine based on whether that smoker smoked "light" or low tar cigarettes, or regular full-flavored cigarettes.<sup>11</sup> Many of the commenters stated that the tar and nicotine yields derived from the Cambridge Filter method are misleading to consumers.<sup>12</sup> Some commenters cited studies indicating that consumers mistakenly believe that lower yield cigarettes confer a reduced risk of harm relative to higher yield cigarettes.<sup>13</sup>

<sup>7</sup> The commenters are the American Academy of Pediatrics, the American Cancer Society Cancer Action Network, American Legacy Foundation, Dr. A. Brandt, Campaign for Tobacco Free Kids (joined by 19 health-related organizations), Dr. G. Connolly, Dr. M. Eriksen, Joanie Fogel, M. Hauckq, K. Karnes, D. Kasper, P. Konigsberg, Konigsberg, Senator Lautenberg (joined by 15 additional Senators), Dr. J. Love, Dr. D. Lynch, A. Moore, NYC Department of Health and Hygiene, Dr. R. O'Connor, Partnership for Prevention, M. Reilly, Smokefree Pennsylvania, Dr. M. Thun, Dr. N. Benowitz, Dr. D. Burns, Dr. K. Warner, and the World Health Organization ("WHO").

<sup>8</sup> Thun.

<sup>9</sup> E.g., Brandt, Kasper, NYC Dept. of Health.

<sup>10</sup> E.g., Campaign for Tobacco Free Kids, American Academy of Pediatrics, Connolly, Hackq, Benowitz, Burns, WHO.

<sup>11</sup> E.g., American Legacy Foundation, Campaign for Tobacco Free Kids, Connolly.

<sup>12</sup> E.g., American Legacy Foundation, Brandt, Campaign for Tobacco Free Kids, Connolly, Eriksen, Karnes, Lautenberg, Moore, O'Connor, Partnership for Prevention, Thun, Warner, WHO.

<sup>13</sup> E.g., Thun.

#### 2. Likely Effects of Rescinding the 1966 Guidance

Some of the commenters stated that rescinding the 1966 Guidance would help ensure that consumers are not misled and would lead to a better public understanding that lower yield cigarettes do not reduce health risks caused by smoking.<sup>14</sup> Other commenters indicated that rescinding the guidance would facilitate smoking cessation by eliminating deceptive claims.<sup>15</sup> One commenter stated that rescinding the guidance would allow consumers to make more informed choices about cigarettes by no longer permitting information that minimizes the health risks associated with smoking.<sup>16</sup> Another indicated that rescission of the guidance was likely to have positive effects on smoking intensity, brand choice, and/or attempts to quit smoking.<sup>17</sup> One organization stated that Commission withdrawal of the guidance would help public health organizations be more effective in their efforts to support smoking cessation and to prevent youth initiation of smoking.<sup>18</sup>

### B. COMMENTS OPPOSING THE PROPOSAL

The Commission received comments opposing its proposal from the four major domestic cigarette manufacturers, and three individuals.<sup>19</sup>

#### 1. Comments from Individuals

One individual, affiliated with a smoking cessation program, indicated that the current test method provides useful information to consumers trying to quit smoking by allowing them to choose brands that have very low yields of nicotine as an initial part of the cessation process.<sup>20</sup> The other two individuals stated that the FTC should fix the existing method rather than rescind its guidance.<sup>21</sup> One of these comments added that once the test method is fixed, the FTC should amend its guidance to require companies to test not only tar, nicotine, and carbon monoxide yields, but also other identified toxins in tobacco smoke such as aldehydes, benzopyrenes, and

<sup>14</sup> E.g., American Legacy Foundation, Brandt, Eriksen, NYC Dept. of Health.

<sup>15</sup> E.g., Campaign for Tobacco Free Kids, Connolly, Fogel, Karnes, Kasper, Lautenberg, Love, Partnership for Prevention.

<sup>16</sup> NYC Dept. of Health.

<sup>17</sup> Love.

<sup>18</sup> Campaign for Tobacco Free Kids.

<sup>19</sup> Liggett Group LLC, Lorillard Tobacco Company, Philip Morris USA, R.J. Reynolds Tobacco Company, Dr. J. Nitzkin, Dr. R. Shipley, Dr. C. Wright.

<sup>20</sup> Shipley.

<sup>21</sup> Wright, Nitzkin.

tobacco-specific nitrosamines, and to require cigarette companies to disclose those yields on cigarette packages.<sup>22</sup>

#### 2. Industry Comments

Each of the four major domestic cigarette manufacturers stated that the FTC should retain the current guidance. These commenters said that the 1966 guidance, permitting the use of a single standardized test method, the Cambridge Filter method, should be retained until a replacement or supplemental test method is approved.<sup>23</sup> These commenters noted that federal and international scientific authorities currently are exploring means for addressing the limitations of machine-based test methods such as the Cambridge Filter method.

#### a. Basis for Opposition and Likely Effects of Rescission

The industry comments stated three general bases for their opposition to the proposed rescission of the guidance. First, each of the companies stated that elimination of the current guidance will lead to consumer confusion, especially since the existing guidance has been in place for over 40 years.<sup>24</sup> Second, most of the industry commenters indicated that a uniform test method is in the public interest.<sup>25</sup> Two commenters stated that consumers would have no means for evaluating relative yields of cigarettes without a single standardized test method.<sup>26</sup> One company indicated that elimination of the guidance could lead to a new "tar derby" in which companies would use different methods of measuring the yields in their cigarettes, thereby leading to greater consumer confusion.<sup>27</sup> Third, three of the industry comments contended that Commission withdrawal of the guidance would be misguided in light of pending legislation that would give the U.S. Food and Drug Administration ("FDA") jurisdiction over cigarette testing specifically and tobacco generally.<sup>28</sup> These commenters stated that if the legislation is enacted, the FDA might decide to reinstate the Cambridge Filter method or impose a test method at odds with the Commission's proposal. Thus, Commission withdrawal of the guidance now could lead to two upheavals in a relatively short period of time, leading

<sup>22</sup> Wright.

<sup>23</sup> Liggett, Philip Morris, R.J. Reynolds, Lorillard (until DHHS responds to FTC request for recommendations as to whether and how to change the existing test method).

<sup>24</sup> Liggett, Lorillard, Philip Morris, R.J. Reynolds.

<sup>25</sup> E.g., Philip Morris, Liggett, Lorillard.

<sup>26</sup> Philip Morris, Lorillard.

<sup>27</sup> Philip Morris.

<sup>28</sup> Liggett, Lorillard, R.J. Reynolds.

to confusion and unnecessary industry expense.<sup>29</sup> One company also said that rescission of the guidance was unwarranted because the Commission has not presented evidence demonstrating that consumers are misled by the yields derived from the current test method.<sup>30</sup>

b. Require Additional Disclosures as an Alternative to Rescission

Three of the industry comments recommended that the Commission consider the use of disclosures or disclaimers as an alternative to rescission of the guidance. These commenters stated that disclosures or disclaimers would reduce any perceived risk of consumer confusion as to the tar and nicotine yields obtained by the Cambridge Filter method. Liggett suggested that the FTC consider the use of qualifying information or disclosures. Lorillard recommended the use of disclaimers such as “results may vary.” Philip Morris stated that the Commission should consider publishing additional consumer education such as an FTC Consumer Alert explaining the limits of the Cambridge Filter method, or require specific disclosures or disclaimers that would decrease the likelihood of consumer confusion.

c. Use of Terms That State or Imply FTC Endorsement

In its **Federal Register Notice** seeking public comment, the Commission stated that advertisers should no longer use the phrase “by FTC Method” or other terms or phrases that state or imply the Commission’s approval or endorsement of the Cambridge Filter method, or yields derived from such method, if the 1966 guidance were rescinded. None of the cigarette companies, nor other commenters, raised any objections concerning this issue. Liggett requested guidance as to whether companies would be able to use terms such as “by Cambridge Method” as an alternative to “by FTC Method.”

d. Effective Dates

The industry comments noted that the Commission did not specify any effective date for compliance if the agency decided to withdraw its guidance. Most of these comments recommended that the FTC provide at least a one-year interim period.<sup>31</sup>

### III. DISCUSSION

After considering all of the comments, the Commission has decided to

withdraw its 1966 guidance. Advertisers who include statements of tar and nicotine yields as measured by the Cambridge Filter method must ensure that such claims comport with the FTC Act. In addition, advertisers should no longer use the phrase “by FTC Method” or other terms or phrases that state or imply the Commission’s approval or endorsement of the Cambridge Filter method, or yields derived from that method or other machine-based test methods.

1. Basis for the Commission’s Rescission of the 1966 Guidance

The Commission has reached this decision for several reasons. First, the underlying premise for the Commission’s guidance was that tar and nicotine statements based on the Cambridge Filter Method would help consumers make informed decisions by providing a metric for reducing their risk of adverse health effects from smoking. There is now a consensus among the public health and scientific communities that the Cambridge Filter method is sufficiently flawed that statements of tar and nicotine yields as measured by that method are not likely to help consumers make informed decisions. Thus, the underlying premise of the 1966 guidance is no longer valid.

In addition, the Commission believes the statements of tar and nicotine yields as measured by this test method are confusing at best, and are likely to mislead consumers who believe they will get proportionately less tar and nicotine from lower-rated cigarettes than from higher-rated brands. The Commission will not allow its stamp of approval on a test method that is confusing or misleading to consumers.

Finally, removal of any reference to the FTC should substantially improve consumer education efforts. It is difficult for the FTC or public health officials to discuss the limitations of ratings obtained pursuant to a test method that is stated to be a method apparently endorsed by an agency of the federal government. For example, the Commission’s consumer alert on tar and nicotine yields conveys an overall message that consumers should not trust the tar and nicotine numbers, while at the same time, cigarette brand advertising implies that the FTC is endorsing those numbers.

2. The Proposed Alternatives Are Inadequate

Given the inherent limits of the Cambridge Filter method, the Commission does not believe that retaining the guidance until approval of a new test method is a viable

alternative. The FTC does not have the specialized scientific expertise needed to design and evaluate scientific test methodologies. Thus, when evaluating medical or other scientific issues, the Commission often relies on other governmental agencies and outside experts with more knowledge in the relevant area. Accordingly, in 1994, the Commission asked the NCI to convene a consensus conference to address cigarette testing issues, and, in 1998, the FTC asked the Department of Health and Human Services for recommendations concerning whether and how to change the test method.<sup>32</sup> There currently does not appear to be a scientific consensus on these issues. Nor is there any anticipated date for reaching a resolution of these issues. Thus, simply waiting until the issues are resolved does not appear warranted or reasonable.

Similarly, the Commission is not convinced that simply amending the guidance to require the addition of disclosures or disclaimers is an adequate alternative to rescission of the guidance.

Likewise, the Commission does not agree that rescission of the guidance is unwarranted or ill-advised because pending legislation would give the FDA jurisdiction over cigarette testing specifically, and tobacco generally. Legislation vesting the FDA with jurisdiction over tobacco products has been introduced annually for over a decade and has yet to be enacted.<sup>33</sup> Most tobacco manufacturers have opposed that legislation, and it is not clear when such legislation may be enacted into law. Moreover, given the clear scientific consensus concerning the inherent limitations of the Cambridge Filter method, it is not likely that the FDA would reimpose a uniform system of cigarette testing that required use of the Cambridge Filter method as it exists today.

<sup>32</sup> See *supra* note 3.

<sup>33</sup> The Commission notes that it has long recommended that Congress consider giving authority over cigarette testing to one of the federal government’s science-based public health agencies. See, e.g., Prepared Statement of the Federal Trade Commission Before the Committee on Commerce, Science, and Transportation, United States Senate (November 13, 2007); Prepared Statement of the Federal Trade Commission Before the Committee on Energy and Commerce, Subcommittee on Commerce, Trade, and Consumer Protection, United States House of Representatives (June 3, 2003); Prepared Statement of the Federal Trade Commission Before the Committee on Government Reform, United States House of Representatives (June 3, 2003); Report to Congress for 1997, Pursuant to the Cigarette Labeling and Advertising Act (July 1999).

<sup>29</sup> E.g., R.J. Reynolds, Lorillard.

<sup>30</sup> Lorillard.

<sup>31</sup> Liggett, Philip Morris, and R.J. Reynolds.

### 3. Requests for Guidance Concerning Future Tar and Nicotine Statements

The comments submitted by the cigarette manufacturers requested guidance on several issues. In particular, Lorillard asked whether Commission rescission of its 1966 guidance would permit companies to include any statements of tar and nicotine yields in future cigarette advertisements.<sup>34</sup> The Commission's rescission of its guidance does not prohibit statements of tar and nicotine yields as long as those claims are truthful, non-misleading, and adequately substantiated. If a claim is not likely to mislead, advertisers can generally make such a claim without running afoul of the FTC Act. At the same time, companies must ensure that their claims do not erroneously convey the impression that the stated yields are the amounts of tar or nicotine a consumer is actually likely to inhale from cigarette smoke, or convey an erroneous or unsubstantiated message that a relatively lower yield cigarette presents a reduced risk of harm.<sup>35</sup>

Liggett requested guidance as to whether companies could include reference to the "Cambridge Filter method" rather than the "FTC method" in any future advertisements. The Commission's rescission of its 1966 guidance does not prohibit companies from referencing the specific test method used to measure any stated yields of tar or nicotine. Future claims will be evaluated under the FTC Act's prohibition against deceptive acts or practices. Thus, companies can make claims that reference a specific test method as long as the claims are truthful, non-misleading, and substantiated. Companies should ensure that such claims do not falsely state or imply the FTC's endorsement or approval of that method.

<sup>34</sup> Lorillard likewise asked whether companies were still required to state tar and nicotine yields in cigarette advertisements pursuant to a 1970 agreement among major cigarette manufacturers. The Commission notes that it is not a signatory to that agreement, and has never required statements of tar and nicotine yields in cigarette advertisements. See Brief of the United States as Amicus Curiae in Support of Respondent, *Altria Group, Inc. v. Good*, No. 07-562 (U.S. Sup. Ct. June 2008).

<sup>35</sup> For example, broad, unqualified claims that emphasize a product feature that may have no relative or actual significance or benefit to consumers, or that fail to disclose information necessary to eliminate a misleading impression, or that deceptively imply a comparative benefit could pose concerns under the FTC Act. See, e.g., Deception Policy Statement, appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984), cited with approval in *Kraft, Inc. v. FTC*, 970 F.2d 314 (7th Cir. 1992), cert. denied, 507 U.S. 909 (1993).

### 4. Dates

The Commission understands that packaging, advertising, and marketing materials that relied on the 1966 guidance may already be in channels of distribution and cannot be readily withdrawn. In the exercise of its prosecutorial discretion, the Commission does not intend to challenge actions taken in reliance on that guidance under circumstances in which altering or withdrawal of the materials was impracticable. Specifically, the Commission will not consider any challenges, prior to January 1, 2009, to materials that conformed to the 1966 guidance. Additionally, the Commission will not consider challenges to point-of-sale materials before March 1, 2009; to print advertisements that have already been distributed to publishers for publication before March 1, 2009; or to inventories of cigarette packaging distributed before March 1, 2009, to the extent that those packaging materials were printed before January 1, 2009.

### 5. Use of Descriptors

Cigarette manufacturers have adopted descriptive terms such as "light" and "ultra low" based on ranges of machine-measured tar yields. The Commission has neither defined those terms, nor provided guidance or authorization as to the use of descriptors. Thus, the Commission did not address, nor did it seek comment on, the use of descriptors in its July 14, 2008 **Federal Register Notice**. Nonetheless, a number of comments raised the use of descriptors. In particular, several of the comments supporting Commission rescission of the 1966 guidance recommended that the Commission ban any use of descriptors.<sup>36</sup> Several of the industry comments, on the other hand, requested guidance as to their continued use of descriptors.<sup>37</sup>

The Commission declines the invitation to initiate a proceeding that would prohibit all use of descriptors. Cigarette manufacturers have been banned from using descriptors by the trial judge in the RICO lawsuit brought by the U.S. Department of Justice,<sup>38</sup> although that remedy is one of the issues currently before the court of appeals. Accordingly, Commission

<sup>36</sup> E.g., American Academy of Pediatrics, American Legacy Foundation, O'Connor, Brandt.

<sup>37</sup> Liggett, Lorillard, R.J. Reynolds, Philip Morris indicated that it did not address the use of descriptors in its comment in light of the Commission's **Federal Register Notice** and on-going litigation.

<sup>38</sup> *U.S. v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006).

action to ban the use of descriptors appears unwarranted at this time.

At the same time, any continued use of descriptors is subject to the FTC Act's proscription against deceptive acts and practices. To the extent that descriptors are used in a manner that conveys an overall impression that is false, misleading, or unsubstantiated, such use would be actionable. Thus, companies must ensure that any continued use of descriptors does not convey an erroneous or unsubstantiated message that a particular cigarette presents a reduced risk of harm or is otherwise likely to mislead consumers.

### IV. CONCLUSION

Based upon the analysis discussed above, the Federal Trade Commission has rescinded its 1966 guidance that it generally is 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." 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.

By direction of the Commission.

**Donald S. Clark**

Secretary

### CONCURRING STATEMENT OF COMMISSIONER PAMELA JONES HARBOUR

*Regarding Federal Register Notice Rescinding the FTC's 1966 Guidance Concerning the Cambridge Filter Method*

Today, the Commission has taken a bold step: removing its apparent imprimatur from cigarette advertisements. This action, while commendable, should only be a first step. Further action is needed.

Contrary to recent criticism,<sup>1</sup> the FTC has not been a passive player in the area of tobacco advertising. The Commission has long advocated for the development of a new test for tar and nicotine.<sup>2</sup> The Commission has sought assistance from the scientific community to determine what changes should be made to the testing method. There still is no consensus on this issue, however, and this lack of agreement has led the Commission to rescind its outdated guidance.

Tobacco companies will no longer be able to use terms indicating that the FTC approves

<sup>1</sup> See Jerry Markon, *Suit on Tobacco Ads Sparks Feisty Debate*, Washington Post, Oct. 7, 2008, at A02.

<sup>2</sup> See Prepared Statement of the Federal Trade Commission Before the Committee on Commerce, Science, and Transportation, United States Senate (November 13, 2007), (<http://www.ftc.gov/os/testimony/P064508tobacco.pdf>).

or endorses the Cambridge Filter Method. The Commission also has clarified that if tobacco firms choose to make claims based on this discredited testing method, these claims will not enjoy any presumption of legitimacy. Going forward, advertisements for cigarettes, like any other ads, will continue to be scrutinized under Section 5 of the FTC Act.

Now that the FTC has removed its apparent imprimatur from the testing method, I urge the scientific community to redouble its efforts. Scientists must develop a test that provides consumers with a meaningful measure of the tar and nicotine yields of the cigarettes they smoke.

More importantly, I urge the next Congress to reintroduce S. 625, the Family Smoking Prevention and Tobacco Control Act. This bill includes several key consumer protection measures. First, the bill allows the Food and Drug Administration to regulate tobacco products. The FDA has lacked any authority in this area for decades, and tobacco manufacturers have exploited the void. The bill would authorize FDA scientists to track, analyze, and regulate the components of tobacco products. If this legislation is enacted, the FDA will wield more effective tools to protect public health.

Second, the bill properly assigns authority to the FDA to issue certain regulations concerning tar and nicotine yields, including requirements governing the methodology for determining tar and nicotine yields and the public disclosure of information about such yields or other constituents of tobacco smoke. For more than 10 years, the Commission has recommended to Congress that one of the government's science-based public health agencies be given jurisdiction over cigarette testing. The FDA clearly has the requisite scientific expertise for this task.

Third, the bill appropriately preserves coordination between the FTC and the FDA in enforcing labeling and marketing requirements. This kind of enforcement is a core element of the FTC's consumer protection mission. The bill wisely preserves the FTC's jurisdiction over unfair or deceptive cigarette advertising.

The regulation of the manufacture, sale, advertising, and marketing of tobacco products is a tall order, but it is crucial to the health of our country, especially its young people. Smoking is a continuing public health crisis. It deserves to be at the top of the new administration's public health agenda.

### CONCURRING STATEMENT OF COMMISSIONER JON LEIBOWITZ

#### *Regarding Rescission of Guidance on Cigarette Testing Methodology*

Our action today ensures that tobacco companies may not wrap their misleading tar and nicotine ratings in a cloak of government sponsorship. Simply put, the FTC will not be a smokescreen for tobacco companies' shameful marketing practices.

For far too long, tobacco companies have advertised cigarettes using "light" and "low tar" descriptors based on machine-tested tar and nicotine results while knowing that the

cigarettes, when actually smoked by people, would not deliver lower tar or nicotine.<sup>1</sup>

And for far too long, the tobacco industry has attempted to use the FTC imprimatur to imply government endorsement of the tar and nicotine ratings.<sup>2</sup> The implication that this agency had mandated disclosure of the ratings furthered the misconception that the descriptors—and the ratings themselves—said something meaningful about the absolute or relative health characteristics of the cigarettes.<sup>3</sup> To the contrary, the FTC has never required disclosure of tar and nicotine yields, nor authorized the use of descriptors.<sup>4</sup>

There's another benefit to our action today. Efforts to educate consumers about the facts behind cigarette ratings—*i.e.*, that the ratings can't predict the amount of tar and nicotine a smoker gets from any particular cigarette, in part because smokers compensate for the lower tar and nicotine yield by inhaling more deeply and smoking longer<sup>5</sup>—will no longer have to battle a contrary message on cigarette advertisements that may have led to consumer confusion about what the ratings really mean.

After today, there should be no confusion: there is no such thing as a safe—or even a safer—cigarette.

[FR Doc. E8-28969 Filed 12-5-08; 8:45 am]

[Billing Code: 6750-01-S]

<sup>1</sup> In the U.S. Department of Justice lawsuit against the major tobacco companies under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), U.S. District Court Judge Kessler ruled that the tobacco company defendants had "falsely marketed and promoted low tar/light cigarettes as less harmful than full-flavor cigarettes in order to keep people smoking and sustain corporate revenues" and that they "internally recognized that low tar cigarettes are not less harmful than full-flavor cigarettes." *United States v. Philip Morris USA*, 449 F. Supp. 2d 1, 430, 456 (D.D.C. 2006); *see also id.* at 430-561. The case is now on appeal.

<sup>2</sup> For example, in defending against a class action lawsuit against manufacturers of "light" and "low-tar" cigarettes, Philip Morris wrongly asserted that the FTC "has required tobacco companies to disclose tar and nicotine yields in cigarette advertising using a government-mandated testing methodology and has authorized them to use descriptors as shorthand references to those numerical test results." Brief for Petitioner Philip Morris at 2, *Altria v. Good*, No. 07-562 (U.S. Mar. 31, 2008).

<sup>3</sup> Tobacco company research conducted literally decades ago—which was never presented to the Commission—indicated that lower tested yields did not entail a reduction in smoke intake. Brief for the United States as Amicus Curiae Supporting Respondents at 9, *Altria v. Good*, No. 07-562 (U.S. June 18, 2008). *See also id.* at 9-11 (setting forth instances where tobacco companies failed to disclose to the Commission, or affirmatively downplayed, effects of compensation); *Philip Morris*, 449 F. Supp. 2d at 431 ("Defendants did not disclose the full extent and depth of their knowledge and understanding of smoker compensation to the public health community or to government regulators.").

<sup>4</sup> *See* Brief for the United States as Amicus Curiae Supporting Respondents at 15, *Altria v. Good*, No. 07-562 (U.S. June 18, 2008).

<sup>5</sup> *E.g.*, FTC Consumer Alert, *Up in Smoke: The Truth About Tar and Nicotine Ratings*, ([www.ftc.gov/bcp/edu/pubs/consumer/alerts/alt069.pdf](http://www.ftc.gov/bcp/edu/pubs/consumer/alerts/alt069.pdf)) (May 2000).

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0038]

### Risk Communication Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Risk Communication Advisory Committee.

*General Function of the Committee:*

To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on February 26, 2009, from 8 a.m. to 5 p.m. and February 27, 2009, from 8 a.m. to 2 p.m.

*Addresses:* Submit electronic comments and information to <http://www.regulations.gov>. Comments are to be identified with the docket number found in brackets in the heading of this document. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on March 31, 2009. All comments received will be posted without change, including any personal information provided. Comments received on or before February 12, 2009, will be provided to the committee before or at the meeting; comments received after that time will still be considered by FDA.

*Location:* National Transportation Safety Board (NTSB) Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594 (at Metro's L'Enfant Plaza station; parking is limited and public transportation is recommended.)

*Contact Person:* Lee L. Zwanziger, Office of the Commissioner, Office of Policy, Planning and Preparedness, Office of Planning (HFP-60), Food and Drug Administration, 5600 Fishers Lane (for express delivery: rm. 15-22), Rockville, MD, 20857, 301-827-2895, FAX: 301-827-3285, Food and Drug Administration, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 8732112560. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications