BEFORE THE
FEDERAL TRADE COMMISSION
OFFICE OF THE SECRETARY
WASHINGTON, D.C.

IN THE MATTER OF:	)	
PROPOSAL TO RESCIND FTC GUIDANCE CONCERNING THE CURRENT CIGARETTE TEST METHOD, [P944509]	)	**FTC-2008-0065**

COMMENTS OF R.J. REYNOLDS TOBACCO COMPANY REGARDING CIGARETTE TESTING METHOD, [P944509]

Communications with respect to this document should be sent to:

Robert F. McDermott, Jr.
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
Telephone: (202) 879-3875
Facsimile: (202) 626-1700
rfmcdermott@jonesday.com

Counsel for R.J. Reynolds Tobacco Company

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Pursuant to the Commission's request for public comment dated July 14, 2008, R.J. Reynolds Tobacco Company ("Reynolds") respectfully submits these comments on the above-captioned proposal, Federal Trade Commission Proposal to Rescind FTC Guidance Concerning Cigarette Test Method, 73 Fed. Reg. 40,350, 40,352 (July 14, 2008) (the "Proposal"). If adopted, the Proposal would rescind the Commission's longstanding guidance governing the testing and disclosure of tar and nicotine yields in cigarettes. After decades under the current FTC Method regime, it would be fundamentally irrational and counter-productive for the Commission to adopt the Proposal at this time in light of pending legislation that, if enacted, would assign these issues to a new agency, thus creating the confusion and expense of two sequential regime changes in the short term. And, in any event, the Proposal should not be adopted without incorporating additional guidance governing important issues such as transition time and descriptors.

I. Adopting The Proposal Would Create Enormous Consumer Confusion And Redundant Cost, And Would Be Misguided In Light Of Prospective Congressional Legislation That Could Assign These Very Issues To A New Regulatory Agency.

The current regime governing tar and nicotine testing has been in effect for decades. Recently, on July 30, 2008, the House of Representatives passed, by a margin of 326-102, H.R. 1108, entitled "The Family Smoking Prevention and Tobacco Control Act" (the "Act"). *See* H.R. 1108, § 101. Parallel legislation is currently pending with 56 sponsors in the Senate. *See* S. 625, 110th Cong. (2008). Reynolds opposes this legislation in its present form, but the Congress has taken these steps toward enacting it, and the reasonable likelihood of this, or some other significant change in the regulatory framework in this area, being adopted cannot be discounted. The Act would vest the FDA with authority to promulgate and enforce "tobacco product standards" limiting nicotine yields and reducing or eliminating "other constituents" of tobacco products. *Id.* § 101 (to be codified as 21 U.S.C. § 907(a)(4)). The Act would also regulate the

use of "descriptors" in labeling and advertising, including descriptors like "light." *Id.* (to be codified as 21 U.S.C. § 911(b)(2)(A)(ii), (3)).

Most importantly, the Act would vest authority in the Secretary of Health and Human Services to regulate the testing and disclosure of tar and nicotine yields in cigarettes. Section 206 of the Act provides:

> The Secretary [of Health and Human Services] shall, by a rulemaking . . ., determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include . . . [in] each cigarette advertisement . . . or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations.

Id. § 206 (to be codified as 15 U.S.C. § 1333(e)). If enacted in its current form, therefore, the Secretary could adopt *any* methodology for testing tar and nicotine yields — including the longstanding FTC Method. *See id.*

Given this potential transformation of the regulatory landscape by Congress, adopting the Proposal now could needlessly subject consumers, as well as Reynolds and the other cigarette manufacturers, to two sequential regulatory regime changes in rapid succession. Consumers and cigarette manufacturers would first need to adjust their behavior in response to the Proposal and whatever additional guidance the Commission issues. Shortly thereafter, this could very well be overtaken by a newly devised regulatory scheme mandated by Congress. And because the Act presently under consideration contemplates that the Secretary will have "sole discretion" to determine the methodology for testing and disclosing tar and nicotine yields, *see id.*, the Secretary could adopt a regulation completely at odds with the Proposal.

The Commission's rescission of its approval of FTC Method tar and nicotine measurements regime would likely affect the market in fundamental respects, such as the brand naming of products. The Proposal provides no direction regarding the future use of descriptors

such as "light" and "low tar," as discussed more fully below in Part II. Because those descriptors are defined by reference to ranges under the FTC Method, Reynolds and other cigarette manufacturers would most likely respond to the Proposal's adoption by reconsidering their continued use of such descriptors. The confusion among consumers that would result from adopting the Proposal would therefore be severe and widespread. As Reynolds demonstrated in the Justice Department RICO suit against the tobacco industry, if the changes the Proposal could trigger were implemented, consumers may conclude that their brand style of choice no longer exists; or be unable to describe or identify their brand style of choice; or conclude that their brand style of choice has changed in ways in other than its name and advertising. *See* Decl. of J. Brice O'Brien, *United States v. Philip Morris USA Inc., et al.*, No. 99-cv-2496 (D.D.C. Aug. 31, 2006) ("O'Brien Decl.") ¶ 9. This decrease in consumer information will undermine the Commission's goals of maximizing consumer welfare. This consumer confusion would be compounded by any legislation that imposes yet another change in the near future. Consumers would then be needlessly exposed to three different regulatory regimes and corresponding brand naming systems in a short time frame.

The costs to Reynolds and other cigarette manufacturers of complying with these back-to-back changes in the governing legal regime would similarly be enormous and unwarranted. Withdrawing the Commission's guidance on the disclosure of tar and nicotine yields "will result in Reynolds incurring a wide variety of costs which are substantial." *Id.* ¶ 8. Reynolds would need to redesign packaging, advertising and other marketing materials, and would need to modify manufacturing operations to manufacture the new packaging, including trade fixtures and brand name shelf labels, and cause those changes to be implemented in retail stores across the country. *See id.* Compliance with the Proposal would require untold hours of work by Reynolds

employees, cost millions of dollars, and last for months. *See id.* Reynolds could have to re-incur many of these costs if the Act, or similar legislation, is adopted and the Secretary promulgates a tar and nicotine yield regulation different from that contemplated in the Proposal.

The untimeliness of the Proposal is underscored by the still-pending request the Commission has issued to the Department of Health and Human Services for guidance in this area, which the Department of Health and Human Services has indicated will be forthcoming in the wake of Monograph 13. As the Proposal itself observes, the Department of Health and Human Services, at the Commission's request, is currently generating advice regarding the very issues that the Proposal addresses. The National Cancer Institute has stated "that it would work with its sister science-based agencies at DHHS to determine what changes needed to be made to the testing method." Proposal, 73 Fed. Reg. at 40,351 n.4. The Commission observed that it "understands that representatives from agencies within DHHS are continuing to look into these issues." *Id.* This is yet another reason why the Proposal is obviously premature, and would needlessly create confusion and burdens. If HHS gives guidance supporting some different tar and nicotine measurement method, for example, then plainly introducing a disruptive interim regulatory system would be unwarranted and counter-productive.

II. An Adequate Provision For Transition Time And Additional Guidance Would Be Necessary Before The Proposal Can Be Implemented.

If the Commission were to adopt the Proposal notwithstanding the foregoing concerns, additional transition time and guidance would be necessary in order for cigarette manufacturers to comply. Yet the Proposal fails to address several issues crucial to the contemplated changes. At a bare minimum, the Proposal needs to allow a reasonable time for cigarette manufacturers to make the appropriate changes. As shown in Part I, this includes likely brand name changes to

eliminate descriptors and creation and distribution of new marketing materials. Apart from its great expense, this would require significant time to accomplish nationwide.

Recognizing the significant burdens associated with compliance, other governmental entities have provided cigarette manufacturers reasonable transition periods to achieve compliance with similar regulatory changes, most commonly at least one year in duration. For example, the European Union afforded cigarette manufacturers more than a year to achieve compliance, even though such compliance was arguably easier than compliance with the Proposal would be. *See* Directive 2001/37/EC, 2001 OJ (L194) 26 (establishing restrictions on use of descriptors and providing more than one year of transition time). In addition, the legislation being actively considered in Congress contemplates a twelve-month transition window for cigarette manufacturers to achieve compliance with its new labeling requirements. *See* H.R. 1108, § 101 (to be codified as 21 U.S.C. § 911(b)(2)(A)(ii), (3)). If the Commission were to adopt the Proposal at this time, a comparable transition period would, at a bare minimum, be necessary.

Any adoption of the Proposal should also incorporate additional guidance both to clarify what changes are required and to facilitate those changes. The issue of descriptors, in particular, requires significant clarification. The Proposal claims that it "does not address the use of descriptors" such as "light" or "low tar." Proposal, 73 Fed. Reg. at 40,352 n.6. The Proposal suggests that the Commission "has not defined those terms, nor provided guidance or authorization as to the use of descriptors." *Id.* But existing consent decrees and other Commission statements *do* discuss the scope and permissible use of such descriptors. In a 1971 consent decree resolving claims against a cigarette manufacturer that characterized brands as "lower" in tar without substantiation by the FTC Method, the Commission reaffirmed that it

would permit the use of descriptive terms such as "low," "lower," "reduced," and "like qualifying terms" where their use was substantiated by FTC Method results and was accompanied by disclosure of the underlying tar and nicotine yields. *See In re Am. Brands, Inc.*, 79 F.T.C. 255, 258-59 (1971). Years later, in another consent decree, the Commission again reaffirmed that "express or implied representation[s] that [a] brand is 'low,' 'lower,' or 'lowest' in tar and/or nicotine" are not misleading or deceptive if those representations are substantiated by FTC Method results. *In re Am. Tobacco Co.*, 119 F.T.C. 3, 11 (1995). Before entry of this decree, the Commission described this statement as providing "a limited 'safe harbor' for advertising that complies with certain specific requirements in its use of official tar and nicotine ratings." *The American Tobacco Company; Proposed Consent Agreement With Analysis To Aid Public Comment*, 59 Fed. Reg. 51,980, 51,982 (Oct. 13, 1994). In light of these consent decrees, it is incumbent on the Commission to clarify whether withdrawal of approval of the FTC Method amounts to withdrawal of approval of the use of descriptors, or otherwise provide specific guidance on the continuing permissibility of descriptors. Proposal, 73 Fed. Reg. at 40,352 n.6.

Relatedly, the Proposal should provide guidance regarding whether, and in what manner, cigarette manufacturers such as Reynolds may issue communications designed to inform consumers about the availability and description of products that may receive new names and advertising following adoption of the Proposal. Clearly, such communications would reduce consumer confusion, which is a stated goal of the Proposal, as well as the economic effect of the Proposal upon Reynolds. *See* Proposal to Rescind FTC Guidance Concerning Cigarette Test Method, 73 Fed. Reg. at 40,351; *see also* O'Brien Decl. ¶¶ 7-9. The Proposal should also address whether, and to what extent, the Commission expects the contemplated rescission of guidance to affect existing point-of-sale advertisements that are owned and controlled by

retailers rather than the cigarette manufacturers. "Reynolds estimates that approximately 350,000 retailers sell cigarettes in the country," and "Reynolds has retail contracts with approximately 180,000 retailers, which in turn sell the vast majority of cigarettes sold in this country." O'Brien Decl. ¶ 20. It would be effectively impossible for cigarette manufacturers such as Reynolds to guarantee compliance with an elimination of descriptors based on numerical FTC Method information at all of these nationwide retailers.

CONCLUSION

The Commission should not adopt the Proposal at this time due to Congress's consideration of legislation that could change the regulatory framework and the Department of Health and Human Services's ongoing review of the FTC Method. In the alternative, and at a minimum, if the Commission elects to proceed now, it should not adopt the Proposal as currently formulated, but rather should revise it to incorporate additional guidance on several key issues and accord cigarette manufacturers a one-year transition period to achieve compliance with the Proposal.

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Respectfully submitted,

Robert F. McDermott
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
Telephone: (202) 879-3875
Facsimile: (202) 626-1700
rfmcdermott@jonesday.com

Counsel for R.J. Reynolds Tobacco Company