

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.¹

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.² 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.³ To the contrary, the FTC has never required disclosure of tar and nicotine yields, nor authorized the use of descriptors.⁴

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 longer⁵—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]

¹ 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.

² 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).

³ 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.").

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

⁵ *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) (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

that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On February 26 and 27, 2009, there will be a discussion of different types of prescription drug information currently available to patients in the form of Medication Guides, Patient Package Inserts (PPIs), and Consumer Medication Information (CMI).

CMI is information developed by the private sector and distributed with each prescription at the pharmacy, as provided by law. On August 6, 1996, Public Law 104-180 was enacted and adopted the following goals with regard to CMI: 75 percent of people receiving new prescriptions would receive "useful" written patient information with their prescriptions by 2000, and 95 percent of people receiving new prescriptions would receive "useful" written patient information with their prescriptions by 2006. The committee will review and discuss a recently completed survey designed to assess whether the year 2006 goal was achieved (for results, see committee background, to be posted as described in this document). The committee will also discuss possible next steps for assuring that consumers receive useful written information with their prescriptions.

The survey is a followup to the year 2001 evaluation of the quality of consumer medication information dispensed in community pharmacies (<http://www.fda.gov/cder/reports/prescriptionInfo/default.htm>). To assist the private sector in meeting the year 2006 goal, FDA published a guidance on producing "Useful Written Consumer Medication Information (CMI)" (<http://www.fda.gov/cder/guidance/7139fnl.htm>).

In 1998, FDA published a final rule that required the development of a Medication Guide for a small number of drugs that the agency considered posed a serious and significant health concern (63 FR 66378, December 1, 1998). A Medication Guide is produced by the drug sponsor, reviewed and approved by FDA and is a component of the approved professional product labeling. An FDA public meeting was held in June 2007 to obtain feedback on the development, distribution, comprehensibility and accessibility of Medication Guides. At that meeting, stakeholders voiced a concern that for prescription drugs with both a

Medication Guide and CMI, patients would be getting unnecessarily duplicative information (meeting summary: <http://www.fda.gov/cder/meeting/SummaryPublicHearingMedicationGuides.htm>).

Finally, PPIs are also required for some drugs and are considered part of the approved product labeling, for example, for estrogens and oral contraceptives.

FDA will seek the advice of the advisory committee, and commentary from stakeholders and from the public, for consideration as it considers appropriate next steps to improve the communication of information about prescription drugs to patients.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is or will be available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2009 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 19, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 3 p.m. on February 26 and between approximately 10:30 a.m. and 11:30 a.m. on February 27. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 19, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 20, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Lee L. Zwanziger at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 26, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-28887 Filed 12-5-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Privacy Act of 1974; Establishment of a New System of Records

AGENCY: Office of the Secretary, Interior.

ACTION: Proposed establishment of a new Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (5 U.S.C. 552a), the Office of the Secretary of the Department of the Interior is issuing public notice of its intent to establish a new Privacy Act system of records, DOI-84, "National Business Center Datamart."

DATES: Comments must be received by January 20, 2009.

ADDRESSES: Any persons interested in commenting on this new, proposed system of records may do so by submitting comments in writing to the Office of the Secretary Acting Privacy Act Officer, Linda S. Thomas, U.S. Department of the Interior, MS-116 SIB, 1951 Constitution Avenue NW., Washington, DC 20240, or by e-mail to Linda_Thomas@nbc.gov.

FOR FURTHER INFORMATION CONTACT:

Mark Stover, Chief, Applications Management and Technology Branch, National Business Center, U.S. Department of the Interior, 7301 West Mansfield Avenue, Denver, CO 80235-2230 or by e-mail at Mark_A_Stover@nbc.gov.

SUPPLEMENTARY INFORMATION: The information contained in Datamart is derived from two existing systems