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Dated: October 19, 2005.

Richard E. Greene,

Regional Administrator, Region 6.

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FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The information collection described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act (PRA) (44 U.S.C. 3501-3520). The FTC proposes to issue compulsory process orders to the largest cigarette manufacturers and smokeless tobacco manufacturers in order to obtain information from those companies concerning, inter alia, their sales and marketing expenditures.

DATES: Comments on the proposed information requests must be received on or before November 30, 2005.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to "Tobacco Reports: Paperwork Comment, FTC File No. P054507" 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 G), 600 Pennsylvania Avenue, NW., Washington, DC 20580. Because paper mail in the Washington area and at the Commission is subject to delay, please consider submitting your comments in electronic form (in ASCII format, WordPerfect, or Microsoft Word), as part of or as an attachment to e-mail messages directed to the following e-mail box: TobaccoReports@ftc.gov. 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."¹

All comments should additionally be submitted to: Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission. Comments should be submitted via facsimile to (202) 395-6974 because U.S. Postal Mail is subject to lengthy delays due to heightened security precautions.

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 will be considered by the Commission and will be available to the public on the FTC Web site, to the extent practicable, at <http://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 website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at <http://www.ftc.gov/ftc/privacy.htm>.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the proposed collection of information should be addressed to Michael Ostheimer, Attorney, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Telephone: (202) 326-2699, e-mail: TobaccoReports@ftc.gov.

SUPPLEMENTARY INFORMATION: For nearly forty years, the Federal Trade Commission has published periodic reports containing data on domestic cigarette sales and marketing expenditures by the major U.S. cigarette manufacturers. The Commission has published comparable reports on smokeless tobacco sales and marketing expenditures since 1987. Both reports originally were issued pursuant to statutory mandates. After those statutory mandates were terminated, the Commission continued to collect and publish information obtained from the cigarette and smokeless tobacco industries pursuant to section 6(b) of the FTC Act, 15 U.S.C. 46(b).

More recently, the Commission decided to address its information requests to the ultimate parent of each of the leading cigarette and smokeless tobacco manufacturers in order to ensure that no relevant data from affiliated companies go unreported. This change presumably increases the

number of separately incorporated entities affected by the Commission's requests.

The FTC proposes to send information requests on an annual basis to the ultimate parent company of each of the five largest cigarette companies and each of the five largest smokeless tobacco companies in the United States ("industry members"). The information requests will seek data regarding, inter alia: (1) The tobacco sales of industry members; (2) how much industry members spend advertising and promoting their tobacco products, and the specific amounts spent in each of a number of specified expenditure categories; (3) whether industry members are involved in the appearance of their tobacco products in television shows or movies; (4) how much industry members spend on advertising intended to reduce youth tobacco usage; (5) the events, if any, during which industry members' tobacco brands are televised; and (6) for the cigarette industry, the tar, nicotine, and carbon monoxide ratings of their cigarettes, to the extent they possess such data. The information will be sought using compulsory process under section 6(b) of the FTC Act, 15 U.S.C. 46(b) (hereinafter "6(b) orders").

On May 9, 2005, the FTC sought public comment on its proposed information collection requests to the major cigarette and smokeless tobacco manufacturers. 70 FR 24415. Nine comments were received, which are discussed below.² Pursuant to the OMB regulations that implement the PRA, 5 CFR part 1320, the FTC is providing this second opportunity for public comment while seeking OMB approval for the proposed information requests.

Comments received: The FTC received seven comments supporting the collection and reporting of the data in question. Those comments were from: (1) The Tobacco Free Kansas Coalition, Inc.; (2) Michael P. Eriksen, Sc.D., of the Institute of Public Health at Georgia State University; (3) the California Department of Health Services; (4) the San Luis Obispo County Tobacco Control Coalition; (5) the National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention; (6) the National Association of Attorneys General; and (7) a group of 44 public health organizations, including the American Lung Association, the American Medical Association, and the American Public

¹ 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).

² The comments are available at <http://www.ftc.gov/os/comments/pratobaccoreports/index.htm>.

Health Association. In addition, Philip Morris USA filed a comment raising several issues regarding the proposed information collection.³ Finally, the Commission also received one comment from an individual opposed to the use of federal funds to collect the information at issue.

1. Comments Supporting the Data Collection. The comments from public health and governmental entities supporting the data collection note that the Commission's reports are the only source of comprehensive information about the marketing and promotion activities of the cigarette and smokeless tobacco industries. The Tobacco Free Kansas Coalition, Inc. stated that the data reported by the Commission are essential in trying to establish funding for tobacco prevention and cessation programs. The California Department of Health Services uses the data to assess the rate of expansion of tobacco industry marketing and promotion, in order to prioritize resources among its various tobacco control priorities. The Public Health Service of the Centers for Disease Control and Prevention (PHS-CDC) noted that the Commission's reports are the only data source available for surveillance of industry spending, and are therefore "essential in monitoring industry tactics regarding advertising, including documenting important shifts such as increases in promotional spending." The PHS-CDC also noted that the FTC reports constitute a source of information to monitor industry compliance with restrictions such as the Master Settlement Agreement that resulted from the settlement of 46 states' lawsuits against the tobacco industry, and that the data in those reports are also used to help interpret the results of evaluations of tobacco control programs. The 44 public health organizations stated that the FTC's reports are virtually the only source of reliable information on cigarette and smokeless tobacco marketing and sales, and that they play a "vital role" in enabling government officials, organizations and professional communities to do their work.

Some of the commenters supporting continued data collection did recommend changes that they believed would increase the utility of the Commission's reports. The California Department of Health suggested that the data be reported on a state-by-state basis, rather than the national basis that the Commission has always used, and

that state-by-state data be further broken down to provide, among other things, company-specific or brand-specific data, and marketing expenditures targeting ethnic populations. The PHS-CDC stated that the utility of the Commission's reports could be increased by the provision of detailed information about individual manufacturers' expenditures, as well as brand-specific or brand-category-specific, state-specific and major-media-market-specific information. The 44 public health organizations similarly suggested in their joint comment, among other things, that the Commission report its data on a state-by-state basis, and, to the extent possible given trade secret and confidentiality concerns, by individual company or brand.

The FTC has determined that even if the cigarette and smokeless tobacco companies are able to report their advertising and marketing expenditures on a state-by-state or regional basis, requiring them to do so at this time would likely increase the burden on those companies without a sufficient increase in the utility of the reports. In addition, with regard to data such as the amount spent to promote individual brands of cigarettes or smokeless tobacco and the amount that a particular company spends to promote all of its products, the FTC is prohibited from disclosing such information while it remains confidential commercial information. 15 U.S.C. 46(f). Accordingly, the FTC does not intend to require reporting on a state-by-state or regional basis or release disaggregated expenditure data.

The 44 public health organizations made a number of additional suggestions. First, the organizations suggested that the FTC provide more detailed information about promotional allowance and retail-value-added expenditures. In 2002, the Commission did in fact revise a number of the categories in which advertising and promotional expenses were to be reported by the manufacturers. Those changes included splitting the "retail-value-added" category into two subcategories (retail-value-added involving free cigarettes, and retail-value-added involving free non-cigarette items), and breaking down the "promotional allowance" category into four new categories (price discounts, promotional allowances paid to retailers, promotional allowances paid to wholesalers, and other promotional allowances). The public health organizations do not specify what kind of additional information about these expenditure categories they want.

Second, the public health organizations suggest that the FTC collect information from the top nine companies in the smokeless tobacco and cigarette industries. The Commission has traditionally issued its cigarette and smokeless tobacco information requests to the five or six largest companies in each industry. At this time, it is not necessary for the FTC to increase the number of cigarette and smokeless tobacco industry members from whom it will collect information to 18, as suggested by the 44 public health organizations. In 2003, the five cigarette companies from whom the FTC proposes collecting information were responsible for over 90% of cigarette sales, and the five smokeless tobacco companies were responsible for over 95% of smokeless tobacco sales. It is unlikely that collecting information from 18 companies, as opposed to the 10 to 15 companies contemplated by the FTC, would significantly alter the overall picture of the industries because the leading companies also are responsible for most cigarette and smokeless tobacco advertising. In light of the aggregated nature of the information reported, the incremental benefit of collecting information from increasingly small companies would appear to outweigh the burden on those companies.

Finally, the public health organizations made a number of additional suggestions, including a request that the FTC report cigarette company television advertising regarding their charitable activities. The FTC will consider these suggestions when it next issues 6(b) orders to the cigarette and smokeless tobacco companies for sales and marketing expenditure data, bearing in mind not only the potential benefits to those who desire the information, but also the feasibility of requiring the companies to provide that information and the burden of requiring them to do so.

2. Comment Opposing the Data Collection. The sole comment opposing the data collection objected to the expenditure of taxpayer money for the purpose of collecting the data in question, stating that "if the tobacco industry wants it, let them pay for it." This comment appears to be based on the erroneous assumption that the Commission collects the data in question for the benefit of the cigarette and smokeless tobacco companies.

3. Comment of Philip Morris USA. Philip Morris USA took no position on the proposed collection of information and offered no comment on the FTC staff's estimate of the burden of the proposed collection. It did, however,

³ Philip Morris USA was the only cigarette or smokeless tobacco company to submit a comment in response to the Commission's notice.

comment on ways to enhance the quality of the information that the Commission proposes to collect, and on ways to minimize the burden imposed on tobacco companies in responding to the Commission. Specifically, Philip Morris suggested that the Commission: (1) Identify the companies from which it seeks data based on a particular sales volume or market share, instead of from a preset number of companies; (2) solicit information from the tobacco companies on a predetermined schedule; (3) increase from 60 days to 90 days the amount of time provided to the companies to submit the requested data; (4) announce in advance any changes in the kinds of data to be collected or in the ways that specific data should be reported; (5) allow advertising and promotional expenditure data to be reported to the nearest \$1,000, rather than to the dollar; and (6) allow expenses to be reported based on generally accepted accounting principles.

Philip Morris suggests that the FTC use sales volume or market share benchmarks to identify those companies to whom it will send information requests. The FTC does, in fact, consider changes in industry market share in determining whether requests should be issued to new companies that have not previously received them, but does not believe it must adopt any one specific mechanism for determining to whom it will issue information requests. Insofar as the FTC is asking for clearance from OMB under the PRA to send information requests to up to 15 companies, it will retain the flexibility to adapt to major changes in either industry.

Philip Morris suggests several reasonable ways to decrease the burden on the cigarette and smokeless tobacco companies. Accordingly, after the first set of 6(b) orders, which will be issued after the FTC obtains OMB clearance to do so, the FTC will attempt to issue its 6(b) orders in the second calendar quarter of the year; unforeseen events may, however, change this schedule in any particular year. The FTC will also extend the time period for companies to submit their responses from 60 days to 90 days, and permit advertising and promotional expenditure data to be reported to the nearest \$1,000. Furthermore, the FTC intends that expenses be reported based on generally accepted accounting principles, and Philip Morris's suggestion provides an opportunity to clear up any confusion on this issue.

Philip Morris states that it would like advance notice of any changes to the information requirements in the 6(b)

orders. The FTC provided advance notice of certain relatively significant changes to the cigarette and smokeless tobacco 6(b) orders in 2002, so that the companies would have additional time to prepare for these changes. The FTC will consider whether any additional burden on the companies from relatively minor changes in the reporting requirements will be outweighed by the costs of the significant delay in obtaining the data that would result from providing advance notice.

Estimated hours burden: The FTC staff's estimate of the hours burden is based on the time required to respond to each information request. Although the FTC intends to issue the information requests only to the five largest cigarette companies and the five largest smokeless tobacco companies (for a total of ten information requests), the burden estimate is based on up to 15 information requests being issued per year to take into account any future changes in these industries. Because these companies vary greatly in size, in the number of products that they sell, and in the extent and variety of their advertising and promotion, the staff has provided a range of the estimated hours burden. Based upon its knowledge of the industries, the staff estimates that the time required to gather, organize, format, and produce their responses ranges between 30 and 80 hours per information request for all but the very largest companies. The very largest companies could require hundreds of hours per year. Thus, the staff estimates a total of 1,800 hours per year, with an average burden per company for each of the intended ten recipients of 180 hours. The staff estimates that for possible additional recipients, which would be smaller companies, the burden should not exceed 300 hours (60 hours per company $\times$ 5 companies). Thus the staff's estimate of the total burden is 2,100 hours. These estimates include any time spent by separately incorporated subsidiaries and other entities affiliated with the ultimate parent company that has received the information request.⁴

Estimated cost burden: It is not possible to calculate with precision the labor costs associated with this data production, as they entail varying compensation levels of management and/or support staff among companies of different sizes. Financial, legal, marketing, and clerical personnel may be involved in the information

collection process. The staff assumes that professional personnel will handle most of the tasks involved in gathering and producing responsive information, and have applied an average hourly wage of \$150/hour for their labor. The staff's best estimate for the total labor costs for up to 15 information requests is \$315,000.

The staff estimates that the capital or other non-labor costs associated with the information requests are minimal. Although the information requests may necessitate that industry members maintain the requested information provided to the Commission, they should already have in place the means to compile and maintain business records.

William Blumenthal,
General Counsel.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Department of Health and Human Services, Office of the Secretary.
ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a meeting. The meeting is open to the public.

DATES: The meeting will be held on November 29, 2005, from 9 a.m. to 5 p.m., and on November 30, 2005, from 9 a.m. to 3:30 p.m.

ADDRESSES: Department of Health and Human Services; Hubert H. Humphrey Building, Room 705-A; 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Ms. Emma English, Program Analyst, National Vaccine Program Office, Department of Health and Human Services, Room 443-H Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; (202) 690-5566, nvac@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 2101 of the Public Service Act (42 U.S.C. 300aa-1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse

⁴ The staff's burden estimate takes into account that the first request to the five smokeless tobacco companies may cover data for three calendar years.