

PATTON, BOGGS & BLOW

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August 9, 1989

BY HAND

Honorable James F. Rill
Assistant Attorney General
Antitrust Division
Department of Justice
Washington, D.C. 10530

Re: Smokeless Tobacco Manufacturers
- Request for Business Review Letter

Dear Mr. Rill:

This is a request for a Business Review Letter under the Business Review Procedure of the Antitrust Division of the Department of Justice, 28 C.F.R. § 50.6, submitted on behalf of the following manufacturers of smokeless tobacco products:

1. United States Tobacco Company
2. Brown & Williamson Tobacco Corporation
3. The Pinkerton Tobacco Company
4. Helme Tobacco Company
5. National Tobacco Company
6. Conwood Company
7. R.C. Owen
8. Byfield Snuff Company
9. House of Windsor, Inc.

Tobacco products manufactured by these smokeless tobacco companies include chewing tobacco, moist snuff, dry/scotch snuff and plug/twist chewing tobacco.

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The companies listed above, representing virtually all of the domestic smokeless tobacco industry,^{1/} request a statement of the Department's present enforcement intentions, based on the representations contained in this letter, with respect to a proposed joint research project to develop uniform analytical methods for measuring the nicotine and moisture content of smokeless tobacco products. This joint research effort is proposed to be undertaken at the specific request of the Office on Smoking and Health of the Department of Health and Human Services ("HHS").

I. Background

Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. § 4403(a)(1)(B) (the "Act"), manufacturers of smokeless tobacco products are required to submit an annual report to HHS stating the nicotine content of their products. The above-named manufacturers of smokeless tobacco products have been requested by HHS and have agreed to provide the moisture content of their products as well. This additional information has been requested because moisture content influences the measurement of nicotine content over time as the products lose moisture through normal drying of the tobacco. The Act does not specify an official method(s) for analyzing smokeless tobacco products for nicotine or moisture levels.

Currently, the closest approximation of a uniform method for analyzing smokeless tobacco products for nicotine and moisture content are the methods of analysis endorsed by the Association of Official Analytical Chemists ("AOAC").^{2/} The AOAC methods, however, are inadequate for purposes of satisfying the reporting requirements under the Act, being generally regarded within the industry as antiquated, unnecessarily time consuming and costly. Additionally, some types of smokeless tobacco products, including plug tobacco, cannot be tested by the AOAC methods due to the consistency of the product (i.e., the samples cannot be prepared as per the stated method).^{3/} Consequently,

1/ The smaller manufacturers of smokeless tobacco products consist primarily of small, sole proprietorships (e.g., country stores which package tobacco locally).

2/ Official Methods of Analysis, Association of Official Analytical Chemists, 13th Edition (1980).

3/ Aside from the AOAC methods of analysis, other well-
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manufacturers of smokeless tobacco products have either adapted the AOAC methods or used newer, more rapid and sophisticated, methods of nicotine and moisture analysis. Thus, a variety of analytical methods are in use within the industry.

Each of the above-named companies has determined that its analytical methods produce results equivalent or better than those produced using the AOAC methods. Nevertheless, in anticipation of the Act's reporting requirement, HHS has now requested that the smokeless tobacco industry develop uniform analytical methods. The Act obligates manufacturers to submit nicotine content information to HHS (and moisture content, as requested by HHS) and authorizes HHS, based on that information, to inform Congress of any matter "determined to be in the public interest." The Office on Smoking and Health, to which the Secretary of HHS has delegated the responsibilities under the Act, has determined that in order to ensure that reliable and accurate information about the nicotine and moisture content of smokeless tobacco products is provided to it under the Act, manufacturers of smokeless tobacco products must use uniform analytical methods. Establishing uniform analytical methods will ensure the comparability of data received from the manufacturers of smokeless tobacco products and, according to HHS, the validity of its analysis and conclusions regarding nicotine and moisture levels in smokeless tobacco products on an industry-wide basis.

II. Necessity of Collaboration

Development of uniform analytical methods to measure the nicotine and moisture content of smokeless tobacco products requires industry-wide collaboration. Currently, each manufacturer of smokeless tobacco products employs different methods of nicotine and moisture analysis, depending on the type

recognized methods for determining the amount of nicotine and moisture in raw tobacco exist. Such methods, however, are not suitable for smokeless tobacco products. Similarly, widely accepted methods that measure nicotine in cigarette smoke are inappropriate with respect to smokeless tobacco products. Establishing a uniform method for measuring nicotine and moisture in smokeless tobacco products is further complicated because the various forms such products take (e.g., plug, moist snuff, loose leaf, etc.) require variations in sample preparation, which is an essential part of every validated analytical method.

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of products made, analytical equipment owned, laboratory capabilities, training and experience of laboratory employees, and other similar factors. HHS recognizes that the selection of any analytical methods will be most effective if they have the confidence of and are endorsed by all of the companies required to use the methods. Since any effort by an individual company to develop methods of analysis would likely be inapplicable and/or unacceptable to others in the industry, collaboration in that effort is necessary. Absent the proposed joint effort it is unlikely that such research would be undertaken or that HHS' goal of establishing uniform methods of nicotine and moisture content analysis would be realized.

Collaboration is further necessitated by the practicalities of the smokeless tobacco industry. Most of the expertise regarding these products and regarding analysis of them for nicotine and moisture content resides in industry. It would be difficult to hire independent consultants to conduct the requisite research. HHS has indicated that it is not in a position to conduct the research contemplated; HHS does not have the resources to complete such a project on its own.

III. Type of Research Contemplated

The proposed research effort will commence with the designation by each company of one or more technical experts. The designated experts will evaluate the analytical methods currently used by their respective companies. Testing methods will be judged according to established criteria to determine if the methods are accurate, efficient, sensitive, reliable, etc. The experts will then reach a consensus on what the best methods are and determine whether the utility of any of those methods can be expanded to increase their applicability to the various forms of smokeless tobacco products which are manufactured and sold. It is also conceivable that entirely new analytical methods may need to be devised.

Ultimately, it is anticipated that the experts participating in the research project will devise several methods to measure nicotine and moisture content, each one of which will be suitable for one or more categories of smokeless tobacco products.

Any method judged by the group to be suitable will need to be subjected to a rigorous testing program to establish its validity. It is anticipated that this program will follow

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typical AOAC procedures for method validation. It is also anticipated that completion of the project will be achieved within one to three years. An accurate time frame is difficult to predict, however, given the potential complications associated with the assessment and validation of various test methods for the different types of smokeless tobacco products.

IV. Sharing of Costs and Technical Information

Each company will bear the cost of allowing its technical expert(s) to participate in the joint research effort. The technical costs associated with analytical work will be split among the companies, in roughly equal proportions.

Technical information pertaining to the conduct of current test methods will be exchanged among participants. Conceivably, such information will encompass matters regarding the accuracy, reliability, efficiency, and cost elements of current test methods and data concerning the results of different methods used to analyze different products. Thus, at most, the participants in the joint research effort will share technical data of a very limited nature. The companies will not share information regarding product development, product costs or any other information that might impact on competition in the industry. Neither will the companies engage in collusion with respect to markets in which they are buying or selling.

V. Results of the Joint Research Effort

The results of the joint research effort, uniform analytical methods to measure the nicotine and moisture content of smokeless tobacco products, will be submitted to HHS. It is our understanding that HHS will then conduct its own evaluation of the proposed methods and, assuming they are acceptable, will seek to require use of those methods on an industry-wide basis by specifying the methods that satisfy the nicotine (and moisture) content reporting obligations under the Act.

VI. Effect on Competition

The proposed joint research effort is not being undertaken for any anticompetitive purpose and will not have any significant effect on competition. In fact, the manufacturers of smokeless tobacco products would prefer to continue using their individual methods to measure the nicotine and moisture content of their

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products. They have agreed to collaborate on a uniform testing method project solely at the request of HHS.

The above-named companies seek approval solely to engage in research to develop methods for nicotine and moisture content analysis, an activity that alone has no impact on competition. Any company engaged in the manufacture and distribution of smokeless tobacco products for profit in the United States will be invited to participate in the joint research effort.

No competitors of the participating companies will be significantly disadvantaged by the joint collaboration. Although requiring smaller manufacturers of smokeless tobacco products to comply with the testing procedures developed by larger manufacturers may result in some minimally adverse competitive impact, to the extent that occurs it is the inevitable result of the Congressional mandate to HHS under the Act. The above-named companies have no control over HHS' decision to develop uniform analytical methods or to require that any analytical methods developed be used on an industry-wide basis.

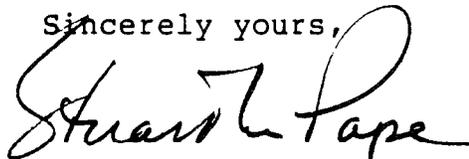
VII. Public Interest

The proposed joint research effort is in the public interest. HHS intends to impose uniform testing methods to ensure comparability of information from diverse sources. Such a result can only be accomplished if the expertise that resides in the smokeless tobacco industry is employed on a collaborative basis.

VIII. Other Matters

This request for a Business Review Letter contains all relevant data and copies of operative documents and references any and all collateral oral understandings. Additionally, we will provide any other information or documents requested by the Division.

Sincerely yours,



Stuart M. Pape
Counsel to the above-named
companies