Appendix 3

FDA Letters to Tobacco Manufacturers

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 11, 1994

Geoffrey C. Bible, CEO
Philip Morris Companies
120 Park Avenue
New York, NY 10017

Dear Mr. Bible:

As part of our ongoing investigation into whether the agency should regulate nicotine-containing cigarettes, FDA requests that your company provide all documents related to all research on nicotine and nicotine analogs, including their pharmacological effects, and all documents relevant to the nicotine in your tobacco products.

Our request includes information related to breeding tobacco, methods of producing nicotine, buying practices, blending, product design, design specifications, manufacturing that relates to nicotine, and additives. We also request all documents relating to any other technology or any chemicals that can affect the concentration or delivery of nicotine from tobacco products or affect the structure or function of the body.

With regard to additives, we request a list of any additives used in your nicotine-containing cigarettes, including those used in your filters and papers, that are not included in the list of 599 additives provided to the Office of Smoking and Health. Further, we request all documents relating to any human or animal testing of any other compounds, which may be added directly or indirectly to tobacco products; all research and information on pyrolysis products resulting from these additives; and all research and information on the toxicology associated with these additives.

Further, this request includes all research and information related to the biology and psychopharmacology of nicotine, all research and information on nicotine using electroencephalography, all nicotine-related research conducted by INBIFO and others on your behalf, and all research and consumer testing on "NEXT" and any other ultra low tar, low nicotine and de-nicotinized products. This request is meant to include research conducted domestically or internationally by your company, any of its affiliates, including any parent corporation, or contractors. In addition, FDA requests that you provide all responsive documents that may be in the possession of the Council on Tobacco Research, the Tobacco Institute, or any other research organization funded in whole or in part by your company. If any responsive documents are not in your possession or control but relate in any way to the information requested above, please identify the names of the companies or organizations to whom you have surrendered control of the documents and disclose any agreements you have with these entities regarding these documents.

In his testimony on June 23, 1994, before the House Subcommittee on Health and the Environment, Thomas Sandefur, President and Chief Executive Officer of Brown and Williamson Tobacco Corporation, stated that he would encourage his employees to speak freely to the subcommittee and to FDA. He also stated on the record that to further the current investigation he would release employees of Brown and Williamson from confidentiality agreements that its employees may have signed as a condition of employment. In the same fashion, we request that you release your employees and contractors from any confidentiality agreements that might preclude them from answering all the agency's questions regarding the use of nicotine in the design and manufacture of your cigarettes.

In order that the agency develop a complete factual record in a timely manner, the FDA requests that Philip Morris disclose any relevant documents or information within thirty days. If you have any questions regarding your response to this letter, please do not hesitate to call Mitchell Zeller at (301) 443-5004.

Sincerely,

Ronald G. Chesemore
Associate Commissioner for
Regulatory Affairs

A-123

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 11, 1994

James W. Johnston, Chairman & CEO
R. J. Reynolds
401 N. Main Street
Winston-Salem, NC 27102

Dear Mr. Johnston:

As part of our ongoing investigation into whether the agency should regulate nicotine-containing cigarettes, FDA requests that your company provide all documents related to all research on nicotine and nicotine analogs, including their pharmacological effects, and all documents relevant to the nicotine in your tobacco products. This letter follows up on a June 10 letter to Mr. Richard Cooper of Williams & Connolly in which FDA asked for either a conference call or a meeting with appropriate R.J. Reynolds representatives to discuss specific issues related to nicotine-containing cigarettes.

Our request includes information related to breeding tobacco, methods of producing nicotine, buying practices, blending, product design, design specifications, manufacturing that relates to nicotine, and additives. We also request all documents relating to any other technology or any chemicals that can affect the concentration or delivery of nicotine from tobacco products or affect the structure or function of the body.

With regard to additives, we request a list of any additives used in your nicotine-containing cigarettes, including those used in your filters and papers, that are not included in the list of 599 additives provided to the Office of Smoking and Health. Further, we request all documents relating to any human or animal testing of any other compounds, which may be added directly or indirectly to tobacco products; all research and information on pyrolysis products resulting from these additives; and all research and information on the toxicology associated with these additives.

Further, this request includes all research and information related to the biology and psychopharmacology of nicotine, all research and information on nicotine using electroencephalography, all nicotine-related research, and all research and consumer testing on any ultra low tar, low nicotine and de-nicotinized products. This request is meant to include research conducted domestically or internationally by your company, any of its affiliates, including any parent corporation, or contractors. In addition, FDA requests that you provide all responsive documents that may be in the possession of the Council on Tobacco Research, the Tobacco Institute, or any other research organization funded in whole or in part by your company. If any responsive documents are not in your possession or control but relate in any way to the information requested above, please identify the names of the companies or organizations to whom you have surrendered control of the documents and disclose any agreements you have with these entities regarding these documents.

In his testimony on June 23, 1994, before the House Subcommittee on Health and the Environment, Thomas Sandefur, President and Chief Executive Officer of Brown and Williamson Tobacco Corporation, stated that he would encourage his employees to speak freely to the subcommittee and to FDA. He also stated on the record that to further the current investigation he would release employees of Brown and Williamson from confidentiality agreements that its employees may have signed as a condition of employment. In the same fashion, we request that you release your employees and contractors from any confidentiality agreements that might preclude them from answering all the agency's questions regarding the use of nicotine in the design and manufacture of your cigarettes.

In order that the agency develop a complete factual record in a timely manner, the FDA requests that R.J. Reynolds disclose any relevant documents or information within thirty days. If you have any questions regarding your response to this letter, please do not hesitate to call Mitchell Zeller at (301) 443-5004.

Sincerely,

Ronald G. Chesemore
Associate Commissioner for
Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 11, 1994

Edward A. Horrigan, CEO
Liggett Group, Inc.
300 N. Duke Street
P.O. Box 1572
Durham, NC 27702

Dear Mr. Horrigan:

As part of our ongoing investigation into whether the agency should regulate nicotine-containing cigarettes, FDA requests that your company provide all documents related to all research on nicotine and nicotine analogs, including their pharmacological effects, and all documents relevant to the nicotine in your tobacco products.

Our request includes information related to breeding tobacco, methods of producing nicotine, buying practices, blending, product design, design specifications, manufacturing that relates to nicotine, and additives. We also request all documents relating to any other technology or any chemicals that can affect the concentration or delivery of nicotine from tobacco products or affect the structure or function of the body.

With regard to additives, we request a list of any additives used in your nicotine-containing cigarettes, including those used in your filters and papers, that are not included in the list of 599 additives provided to the Office of Smoking and Health. Further, we request all documents relating to any human or animal testing of any other compounds, which may be added directly or indirectly to tobacco products; all research and information on pyrolysis products resulting from these additives; and all research and information on the toxicology associated with these additives.

Further, this request includes all research and information related to the biology and psychopharmacology of nicotine, all research and information on nicotine using electroencephalography, all nicotine-related research, and all research and consumer testing on any ultra low tar, low nicotine and de-nicotinized products. This request is meant to include research conducted domestically or internationally by your company, any of its affiliates, including any parent corporation, or contractors. In addition, FDA requests that you provide all responsive documents that may be in the possession of the Council on Tobacco Research, the Tobacco Institute, or any other research organization funded in whole or in part by your company. If any responsive documents are not in your possession or control but relate in any way to the information requested above, please identify the names of the companies or organizations to whom you have surrendered control of the documents and disclose any agreements you have with these entities regarding these documents.

In his testimony on June 23, 1994, before the House Subcommittee on Health and the Environment, Thomas Sandefur, President and Chief Executive Officer of Brown and Williamson Tobacco Corporation, stated that he would encourage his employees to speak freely to the subcommittee and to FDA. He also stated on the record that to further the current investigation he would release employees of Brown and Williamson from confidentiality agreements that its employees may have signed as a condition of employment. In the same fashion, we request that you release your employees and contractors from any confidentiality agreements that might preclude them from answering all the agency's questions regarding the use of nicotine in the design and manufacture of your cigarettes.

In order that the agency develop a complete factual record in a timely manner, the FDA requests that **Liggett Group, Inc.,** disclose any relevant documents or information within thirty days. If you have any questions regarding your response to this letter, please do not hesitate to call Mitchell Zeller at (301) 443-5004.

Sincerely,

Ronald G Chesemore

Ronald G. Chesemore
Associate Commissioner
for Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 11, 1994

Donald S. Johnston, CEO
American Brands
American Tobacco Company
Management Center
P.O. Box 10380
Stamford, CT 06904-2380

Dear Mr. Johnston:

As part of our ongoing investigation into whether the agency should regulate nicotine-containing cigarettes, FDA requests that your company provide all documents related to all research on nicotine and nicotine analogs, including their pharmacological effects, and all documents relevant to the nicotine in your tobacco products.

Our request includes information related to breeding tobacco, methods of producing nicotine, buying practices, blending, product design, design specifications, manufacturing that relates to nicotine, and additives. We also request all documents relating to any other technology or any chemicals that can affect the concentration or delivery of nicotine from tobacco products or affect the structure or function of the body.

With regard to additives, we request a list of any additives used in your nicotine-containing cigarettes, including those used in your filters and papers, that are not included in the list of 599 additives provided to the Office of Smoking and Health. Further, we request all documents relating to any human or animal testing of any other compounds, which may be added directly or indirectly to tobacco products; all research and information on pyrolysis products resulting from these additives; and all research and information on the toxicology associated with these additives.

Further, this request includes all research and information related to the biology and psychopharmacology of nicotine, all research and information on nicotine using electroencephalography, all nicotine-related research, and all research and consumer testing on any ultra low tar, low nicotine and de-nicotinized products. This request is meant to include research conducted domestically or internationally by your company, any of its affiliates, including any parent corporation, or contractors. In addition, FDA requests that you provide all responsive documents that may be in the possession of the Council on Tobacco Research, the Tobacco Institute, or any other research organization funded in whole or in part by your company. If any responsive documents are not in your possession or control but relate in any way to the information requested above, please identify the names of the companies or organizations to whom you have surrendered control of the documents and disclose any agreements you have with these entities regarding these documents.

In his testimony on June 23, 1994, before the House Subcommittee on Health and the Environment, Thomas Sandefur, President and Chief Executive Officer of Brown and Williamson Tobacco Corporation, stated that he would encourage his employees to speak freely to the subcommittee and to FDA. He also stated on the record that to further the current investigation he would release employees of Brown and Williamson from confidentiality agreements that its employees may have signed as a condition of employment. In the same fashion, we request that you release your employees and contractors from any confidentiality agreements that might preclude them from answering all the agency's questions regarding the use of nicotine in the design and manufacture of your cigarettes.

In order that the agency develop a complete factual record in a timely manner, the FDA requests that **American Tobacco Company** disclose any relevant documents or information within thirty days. If you have any questions regarding your response to this letter, please do not hesitate to call Mitchell Zeller at (301) 443-5004.

Sincerely,

Ronald G. Chesemore

Ronald G. Chesemore
Associate Commissioner
for Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 11, 1994

Thomas E. Sandefur, CEO
Brown & Williamson
1500 Brown & Williamson Tower
Louisville, KY 40232

Dear Mr. Sandefur:

As part of our ongoing investigation into whether the agency should regulate nicotine-containing cigarettes, FDA requests that your company provide all documents related to all research on nicotine and nicotine analogs, including their pharmacological effects, and all documents relevant to the nicotine in your tobacco products.

Our request includes information related to breeding tobacco, methods of producing nicotine, buying practices, blending, product design, design specifications, manufacturing that relates to nicotine, and additives. We also request all documents relating to any other technology or any chemicals that can affect the concentration or delivery of nicotine from tobacco products or affect the structure or function of the body.

With regard to additives, we request a list of any additives used in your nicotine-containing cigarettes, including those used in your filters and papers, that are not included in the list of 599 additives provided to the Office of Smoking and Health. Further, we request all documents relating to any human or animal testing of any other compounds, which may be added directly or indirectly to tobacco products; all research and information on pyrolysis products resulting from these additives; and all research and information on the toxicology associated with these additives.

Further, this request includes all research and information related to the biology and psychopharmacology of nicotine, all research and information on nicotine using electroencephalography, all nicotine-related research, and all research and consumer testing on any ultra low tar, low nicotine and de-nicotinized products. This request is meant to include research conducted domestically or internationally by your company, any of its affiliates, including any parent corporation, or contractors. In addition, FDA requests that you provide all responsive documents that may be in the possession of the Council on Tobacco Research, the Tobacco Institute, or any other research organization funded in whole or in part by your company. If any responsive documents are not in your possession or control but relate in any way to the information requested above, please identify the names of the companies or organizations to whom you have surrendered control of the documents and disclose any agreements you have with these entities regarding these documents.

In order that the agency develop a complete factual record in a timely manner, the FDA requests that Brown & Williamson disclose any relevant documents or information within thirty days. If you have any questions regarding your response to this letter, please do not hesitate to call Mitchell Zeller at (301) 443-5004.

Sincerely,

Ronald G. Chesemore

Ronald G. Chesemore
Associate Commissioner for
Regulatory Affairs

Similar letters were also sent to the following tobacco companies:

Andrew Tisch, President and Co-CEO
Lorillard Tobacco Co.
1 Park Avenue
New York, NY 10016

Vincent Gierer, CEO
U.S. Tobacco Company
100 Putnam Avenue
Greenwich, CT 06830

Thomas J. Ryan, CEO and President
Helme Tobacco Company
4 Maple Street
Helmetta, NJ 08828

Robert Seidensticker, President
Pinkerton Tobacco Company
6630 W. Broad Street
Richmond, VA 23230-1702

Tom Helms, President
National Tobacco Company
3029 W. Muhammad Ali Boulevard
Lousiville, KY 40212-2238

J.S. Wilson, CEO and President
Conwood Tobacco Company
813 Ridge Lake Boulevard
Memphis, TN 38120