DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Bethesda MD 20205

February 9, 1987

REGULATORY LETTER

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CERTIFIED

J. Philip Ray, Director
Advanced Tobacco Products Inc.
121 Interpark Boulevard
Suite 108
San Antonio, Texas 78216

Re: Favor Smokeless Cigarettes Regular
Favor Smokeless Cigarettes Menthol
Favor Smokeless Cigarettes Lights
Favor Smoke-Free Cigarettes Regular
Favor Smoke-Free Cigarettes Menthol
Favor Smoke-Free Cigarettes Lights

Ref. No. 87-HFN-312-06

Dear Mr. Ray:

This letter is in reference to your marketed products listed above, Favor Smokeless Cigarettes Regular, Menthol, and Lights; Favor Smoke-Free Cigarettes Regular, Menthol and Lights (Favor). Each Favor consists of a plug impregnated with a nicotine solution inserted within a small tube corresponding in appearance to a conventional cigarette which you have described as a novel nicotine delivery system and a method of administering nicotine by inhalation of nicotine vapor.

We have reviewed labeling and promotional literature of Advanced Tobacco Products, Inc., and other written materials issued by or on behalf of your firm, such as a registration statement filed in January, 1984, with the Securities and Exchange Commission (SEC) (Form S-1, File No. 2-88812), Amendment No. 1 to Form S-1 (filed with the SEC April 17, 1984), Company Responses to SEC Comments (filed with the SEC April 17, 1984), and your form 10-K annual report for the fiscal year ended June 30, 1984 (filed with the SEC October 30, 1984).

The materials referred to above contain statements which represent and suggest that Favor is a novel nicotine delivery system; that each pack of six will have a nicotine delivery capacity intended to satisfy the average smoker of conventional cigarettes for an entire day; that Favor delivers an amount of nicotine per inhalation within a range of amounts delivered per inhalation from many conventional combustible cigarettes; that the quantity of nicotine required to produce the effect on the nervous system which most cigarette smokers are accustomed is small relative to the amounts of other alkaloids regularly consumed by typical users; and that it is an alternative for conventional cigarette smokers who desire nicotine pleasure. A paper submitted to the SEC by or on behalf of your firm, to support your firm's conclusion that Favor and conventional

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cigarettes have the same or equivalent nicotine delivery (Jacobson, Jacobson, and Ray, Nicotine Vapor Inhalation: Alternative Method of Nicotine Delivery), purports to describe a practical and apparently satisfying method of administering nicotine by inhalation of nicotine vapor through a non-combustible cigarette designed by one of the authors (J.P. Ray); states that it is likely that nicotine has addicting qualities and is the primary ingredient which motivates smoking; and states that the authors have demonstrated that meaningful levels of serum nicotine and urine cotinine are achieved by inhalation.

Your materials submitted to the SEC include references to reports in the medical literature concerning the effects of nicotine. The medical literature clearly recognizes that nicotine is well absorbed from the lungs; that it has potent pharmacologic effects, including effects on the nervous system; and that nicotine is a drug of dependence.

In view of the above, it is our position that Favor is a nicotine delivery system intended to satisfy a nicotine dependence and to affect the structure and one or more functions of the body. Because of its intended uses, Favor is a drug as defined within section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). In addition, we regard Favor to be a new drug within the meaning of section 201(p) of the Act because Favor's composition is such that it is not generally recognized, among qualified experts, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling.

Since Favor is a new drug within the meaning of the Act and no approval of an application filed pursuant to section 505(b) of the Act is effective for it, Favor may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Act. Thus, continued marketing of Favor would be in violation of the Act and the marketing of Favor products such as the ones listed above should be discontinued.

We request that you reply within ten (10) days of the receipt of this letter stating the action you will take to discontinue Favors's marketing. If corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products, 21 U.S.C. 332 and 334.

Sincerely yours,

Daniel L. Michels
Director
Office of Compliance
Center for Drugs and Biologics

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