

*file
Legislative
FDA Reg. of tobacco
DIR 3294*

Frank Young, M.D.,
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Young:

It has recently come to my attention that two nicotine containing products have been introduced to the U.S. market that may violate provisions of the Federal Food, Drug and Cosmetic Act. I would appreciate your providing the Subcommittee with an evaluation of whether the content and packaging of "IPCO Creamy Snuff" and "Masterpiece Tobacs" are subject to and consistent with Federal law.

"IPCO Creamy Snuff" is manufactured by Asha Industries of India but apparently distributed in the United States by IPCO Tobacco Products of Philadelphia, Pennsylvania. This product is packaged like toothpaste and contains promotional material recommending that the product is a "New way to quit smoking." The package insert contains the statement that use of the product may pose less of a health risk than smoking.

"Masterpiece Tobacs" is a new product manufactured by The Pinkerton Tobacco Co. of Owensboro, Kentucky. The product is sold in peppermint and cinnamon flavors and by using a gum base, appears to bear a striking similarity to the prescription drug "NICORETTE."

In addition, I would appreciate your supplying the Subcommittee with a description of the extent and limits of the agency's authority over food and drug products containing nicotine. A brief discussion of the regulatory history of "NICORETTE" and any other nicotine containing products considered by the agency would be helpful in this regard.

Please contact Ripley Forbes of the Subcommittee staff at 226-7620, should you have any questions concerning this request. Your response by July 17, 1987 would be greatly appreciated.

With every good wish, I am,

Sincerely,

HENRY A. WAXMAN
Chairman, Subcommittee on
Health and the Environment

HAW/rfs