

D R A F T  
3/28/78

(Tobacco Institute Letterhead)

Mr. Dennis J. Cotter  
Food and Drug Administration  
Bureau of Medical Devices (HFK-430)  
8757 Georgia Avenue  
Silver Spring, Maryland 20910

Re: Socket No. 77D-0367

Dear Mr. Cotter:

Enclosed are comments submitted by The Tobacco Institute with respect to the recommendation of the Anesthesiology Device Classification Panel that "filters, tobacco smoke, attached" be regulated as Class III devices. The comments conclude that, as a matter of law, such filters are not "devices" under the Federal Food, Drug, and Cosmetic Act and accordingly are not subject to FDA jurisdiction.

We hope that the analysis in these comments will be of assistance to the agency in its consideration of the Panel's views.

Sincerely yours,

Horace R. Kornegay

Enclosure

cc: David M. Link, Bureau Director  
Richard M. Cooper, Chief Counsel

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