

REK

SEP 16 1987

Mr. Stuart Pape
Patton, Boggs and Blow
2550 M Street, N.W.
Washington, D.C. 20037

Dear Mr. Pape:

This is in reference to our meeting on February 4, 1987 in which you suggested that "Masterpiece Tobacs" is not a food. You basically argued that it is not a chewing gum because it is a tobacco product that is clearly packaged and labeled as a tobacco product.

We disagree. As you know, the definition of "food" in section 201(f) of the Federal Food, Drug and Cosmetic Act (FD&C Act) includes chewing gum. Masterpiece Tobacs primarily consists of gum, tobacco, sweeteners, and flavoring. It looks, tastes, and chews like chewing gum. Furthermore, because of the flavors and sweeteners in this gum, the saliva is likely to be swallowed as in gum chewing rather than expectorated. Furthermore, it is unlike traditional smokeless tobacco products. Therefore, we believe that Masterpiece Tobacs is a chewing gum, and thus a food under the FD&C Act.

In our opinion this product is an adulterated food because it contains the ingredient tobacco, which is not generally recognized as safe (GRAS) for use in foods, and there is no regulation authorizing the use of tobacco in chewing gum. This product is therefore subject to legal action because it contains a food additive deemed unsafe within the meaning of section 409 of the FD&C Act and is thus considered to be adulterated within the meaning of section 402(a)(2)(C) of the FD&C Act.

We remain concerned about the safety of Masterpiece Tobacs for both adults and for youngsters who might get access to the product and find it attractive. Nevertheless, if your clients intend to use tobacco in this product, they should submit a food additive petition in accordance with 21 CFR 171.1 or a GRAS affirmation petition in accordance with 21 CFR 170.35. Copies of these regulations are enclosed for your clients' assistance. We question whether the safety of tobacco as a food can be established. However, in the event that such safety can be established we would be willing to exempt the product from any ingredient disclosure which would conflict with the confidentiality requirements of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (P.L. 99-252).

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The classification of this product as a food has no bearing on its status as a tobacco product under the Internal Revenue Code. We have been advised that BATF continues to regard this product as a tobacco product which is subject to tax under chapter 52 of the Internal Revenue Code. This product will also continue to be subject to the Comprehensive Smokeless Tobacco Health Education Act of 1986.

These views were discussed during a meeting between yourself, Mr. Steve McNamara and Mr. Bill Gray representing Pinkerton Tobacco Company and Mr. L. Robert Lake, Mr. Philip Derfler and me as well as other members of the Food and Drug Administration. You were also informed that this Center has no regulatory interest in any other product containing tobacco made by your client, nor do we consider any traditional smokeless tobacco to be a food.

If you have any questions, please let us know.

Sincerely yours,



Richard J. Ronk
Acting Director
Center for Food Safety
and Applied Nutrition