



APR 12 1988

Stuart M. Pape, Esq.
Patton, Boggs & Blow
2550 M Street, N.W.
Washington, D.C. 20037-1350

Re: Masterpiece Tobacs

Dear Mr. Pape:

In a letter dated December 1, 1987, you requested that I review Mr. Ronk's letter of September 16, 1987, on the legal status of the Masterpiece Tobacs product. I apologize for the delay in responding to your request.

I have carefully reviewed and considered the position that Mr. Ronk has taken with respect to Masterpiece Tobacs and the arguments that you have made in your letter. On the basis of my review, I have concluded that this product satisfies the definition of a "food" under the Food, Drug, and Cosmetic Act (the FD&C Act), and that as such, it is subject to regulation by FDA.

"Food" is defined in the FD&C Act in section 201(f), 21 U.S.C. 321(f), as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." In his letter, Mr. Ronk stated that Masterpiece Tobacs is a chewing gum and thus a food under the FD&C Act. You have argued, however, that "the mere fact that a product is 'chewable' (i.e., contains a masticatory substance) is not, in and of itself, sufficient to characterize the product as a 'chewing gum' for FDA regulatory purposes." Instead, citing the legislative history of the FD&C Act (Senate Report No. 361), you have argued that FDA should look to the manufacturer's representations as to the intended use of the product in deciding in what category to put a product.

I find that the legislative history you cite, while relevant to the question of whether a product is a food or a drug, is not relevant to the question of whether a product is a food or is not subject to regulation under the FD&C Act. This is the position taken by the court in United States v. Technical Egg Products, Inc., 171 F. Supp. 326 (N.D. Ga. 1959), a case that involved the question of whether incubator reject shell eggs were food. The court stated:

... The test for determining whether an item is a food under the Act cannot be one of intended use. United States v. 52 Drums Maple Syrup, 2 Cir., 110 F.2d 914. It must of necessity be one which regards items as foods which are generally so regarded when sold in food form.

171 F. Supp. at 328.

Masterpiece Tobacs differs from conventional portion-packed snuff not only in the respect that Tobacs uses a masticatory carrier base but also in that it is formed into a hexagon shape that has a smooth, brown, edible outer coating. Although you assert that the brown color was selected to be the color of tobacco, it is also the color of chocolate. Thus, Tobacs has the appearance of a piece of gum, as Mr. Ronk states, or of candy. Consequently, Tobacs is sold in food form and thus is properly regulated as food under the FD&C Act.

The Comprehensive Smokeless Tobacco Health Education Act (CSTHE Act) is not to the contrary. I have carefully considered your discussion of this statute, but I find that the available evidence does not support your claim that this statute was intended to establish an exclusive regulatory scheme for smokeless tobacco products. The CSTHE Act itself sets out the extent to which it was intended to preempt action by other Federal agencies. Section 7(a) of the CSTHE Act, 15 U.S.C. 4406(a), states:

(a) FEDERAL ACTION -- No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 3, shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

As you acknowledge, there is nothing in this preemption provision that would preclude FDA from regulating the composition of a smokeless tobacco product in appropriate circumstances.

Moreover, I do not agree that the finding that Masterpiece Tobacs is a food is contrary to the sanction for the marketing of smokeless tobacco products embodied in the CSTHE Act, or that this finding would render the CSTHE Act a

nullity. FDA's intention is not to establish a general rule for smokeless tobacco products. Our decision is rather the much more limited one that a smokeless product sold in food form is subject to regulation as a food. We believe that this decision only has application to your product, because as far as we know, it is the only smokeless tobacco product being sold in food form. Thus, our decision in no way undercuts the CSTHE Act.

FDA has consulted with the Bureau of Alcohol, Tobacco, and Firearms and the Federal Trade Commission, the other two agencies charged with responsibilities under the CSTHE Act, as to whether they would view FDA's assertion of jurisdiction over your product as a food to be in conflict with the CSTHE Act. Both agencies stated that they would not.

The only conflict between the CSTHE Act and the FD&C Act arises from the fact the former states that manufacturers are to submit ingredient lists to the Department of Health and Human Services, and that those lists are confidential under 5 U.S.C. 552(b)(4). Under the FD&C Act, ingredient lists are to be included on the product label. 21 U.S.C. 343(i)(2).

These provisions are easily harmonized, however, as Mr. Ronk indicated in his letter. There is a proviso to 21 U.S.C. 343(i)(2) that states that FDA can adopt exemptions to the ingredient declaration requirement if the requirement results in unfair competition. Because ingredient confidentiality under the CSTHE Act is based on the Freedom of Information Act exemption for trade secret or confidential commercial information, FDA is prepared to propose an exemption from 21 U.S.C. 343(i)(2) for foods that are subject to the CSTHE Act because disclosing the ingredient list would put the manufacturer at an unfair competitive disadvantage. Such a proposal would be dependent, however, on a showing that tobacco is generally recognized as safe for use in food.

For all the foregoing reasons, I conclude that finding Masterpiece Tobacs to be a food subject to the FD&C Act, as well as the CSTHE Act, does not conflict with the CSTHE Act.

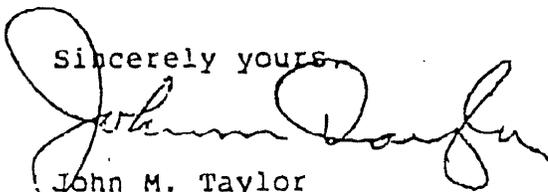
I also find that I cannot accept your arguments with respect to the Fair Packaging and Labeling Act (FPLA), 15 U.S.C. 1451 et seq. You contend that it is significant that the FPLA excludes tobacco products from the definition of "consumer commodity." The section of the FPLA that you rely upon is section 1459(a), which defines "consumer commodity" to mean, among other things, food as defined by the FD&C Act. Section 1459(a) goes on to state that the term does not

include "... any meat or meat product, poultry or poultry product, or tobacco or tobacco product." Because meat and poultry products are clearly foods under the FD&C Act, subject to FDA jurisdiction in appropriate circumstances, and are also excluded from the definition, I do not see the FPLA precluding a product that contains tobacco from being a food under the FD&C Act, and subject to FDA jurisdiction, in the appropriate circumstances.

I agree with Mr. Ronk that Masterpiece Tobacs looks, tastes, and chews like chewing gum or a confection. Because this product is sold in food form, I find that it is appropriately regulated as a food under the FD&C Act.

Please let the Center for Food Safety and Applied Nutrition know within 30 days what your intention is concerning the marketing of this product.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "John M. Taylor".

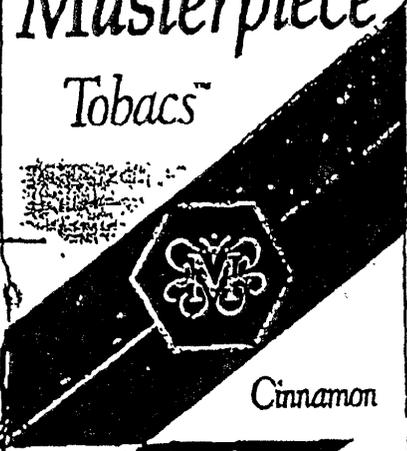
John M. Taylor
Associate Commissioner
for Regulatory Affairs

Masterpiece Cinnamon Tobacs

18 CHEWABLE PIECES

Masterpiece[®] Tobacs™

WARNING: THIS PRODUCT MAY CAUSE
GUM DISEASE AND TOOTH LOSS



Cinnamon

Masterpiece Cinnamon Tobacs

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Masterpiece

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OWENSBORO, KY 40301 U.S.A.
TAX CLASS #1 U.S. PAT. NO. 4,027,189

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18 CHEWABLE PIECES

Masterpiece Tobacs

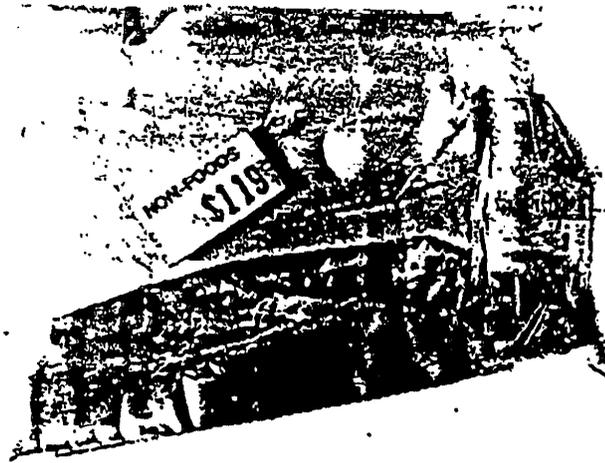
Masterpiece combines a cinnamon flavored
chewable base with the finest quality tobacco
for great tasting tobacco satisfaction
anytime, anywhere.
So when you can't smoke, chew a Masterpiece
Tobac.
This tobacco product is not for use by minors.

Cinnamon

Masterpiece Tobacs

Available in many
flavors. Choose the
Cinnamon flavor tobacco
piece. Just push piece through
the foil and chew.

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OWENSBORO, KY 40301 U.S.A.
TAX CLASS #1 U.S. PAT. NO. 4,027,189



STORE COUPON

60
CENTS
SAVE 60¢
60
CENTS

on one package of New Masterpiece Tobacs™

Detailed description of coupon terms and conditions, including expiration date and usage instructions.

18 chewable pieces

EXPIRATION DATE: March 21, 1988

60
CENTS
60
CENTS

Peppermint Tobacs™

Tobacco Satisfaction
...anytime, anywhere

U.S. PAT. NO. 4624265

ONE DOZEN PACKS • PEPPERMINT

Retailer:

Masterpiece Tobacs is a tobacco product and should be displayed and sold with other tobacco products. The Pinkerton Tobacco Company has a long standing policy that our products will be marketed and sold only to current users of tobacco products who are 18 years of age or older or as specified by state law. We ask that you observe this policy and all state and local laws governing the sale of tobacco products to minors.

The Pinkerton Tobacco Company



Masterpiece®

Tobacco Satisfaction
...anytime, anywhere