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BY HAND

Mr. John M. Taylor  
Associate Commissioner for Regulatory Affairs (HFC-1)  
Food and Drug Administration  
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Dear Mr. Taylor:

I am writing on behalf of The Pinkerton Tobacco Company ("Pinkerton") in reply to a letter of September 16, 1987 from Richard Ronk, Acting Director of the Center for Food Safety and Applied Nutrition, concerning the legal status of Masterpiece "Tobacs." We request your review of the issue addressed in Mr. Ronk's letter.

We strongly disagree with the conclusion stated in Mr. Ronk's letter, i.e., that the Masterpiece "Tobacs" product is subject to regulation by the Food and Drug Administration as a "food." Furthermore, we note that the Agency has not had the opportunity to consider any written statement of our views or the legal authorities we believe to be controlling in this matter (although we did meet with Mr. Ronk and others at the Center in June 1987). Accordingly, we explain below why we believe the "Tobacs" product is properly deemed for regulatory purposes to be a smokeless tobacco product and not a "food."

I. MASTERPIECE "TOBACS" ARE PROPERLY REGARDED AND EXCLUSIVELY REGULATED AS SMOKELESS TOBACCO PRODUCTS

A. The Nature of Smokeless Tobacco Products

Smokeless tobacco in a variety of forms has been marketed in the United States for well over 100 years. In order to under-

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stand why "Tobacs" are properly regarded and exclusively regulated as smokeless tobacco products (and not as food), one must consider the nature and history of smokeless tobacco and its regulation in the United States.

"Smokeless tobacco" is a generic descriptor for a variety of tobacco products that are used or "consumed" through placement in the oral or nasal cavity, rather than through smoking, as with cigarettes, cigars, pipes and the like. Smokeless tobacco products vary not only by brand and type of tobacco (e.g., looseleaf, plug, moist plug and twist chewing tobaccos; dry oral, dry nasal, and moist snuff); but also by type and amount of flavorings and sweeteners; type and amount of binders; moisture content; and tobacco content. Indeed, the flavoring, sweetener, moisture and other elements often play such a significant role in the formulation of smokeless tobacco products that many products, including ordinary looseleaf chewing tobaccos, contain less than 50% tobacco.

Smokeless tobacco products also vary in how they are used by consumers. Some products are inhaled (e.g., dry snuff), some chewed (e.g., looseleaf and plug) and some simply tucked into the mouth and sucked (e.g., moist snuff). Similarly, users typically expectorate with some products (e.g., chewing tobacco), but are less inclined to do so with others (e.g., moist snuff, especially portion-packed varieties). (Since the Center apparently views expectoration as a distinguishing characteristic of smokeless tobacco products, it is particularly important to note that some portion of the tobacco juices are swallowed, rather than expectorated, by users of all chewing tobacco and oral snuff products.)

Although many types and brands of smokeless tobacco have been marketed without change for years, the smokeless tobacco industry has adapted to modern tastes and markets by developing new products as well. One major innovation in recent years was the introduction of portion-packed products (i.e., single portions of smokeless tobacco packaged in tea-bag type pouches). Portion-packed products were designed to be attractive to the growing urban market by eliminating the need to fuss with loose tobacco and reducing the need to expectorate.

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B. Masterpiece "Tobacs"

Masterpiece "Tobacs" simply represent a logical extension of the portion-packed smokeless tobacco concept, and contrary to Mr. Ronk's assertion, "Tobacs" are not "unlike traditional smokeless tobacco products." Rather, as described below, every attribute of the "Tobacs" product is characteristic of smokeless tobacco currently marketed in the United States. Additionally, The Pinkerton Tobacco Company has been scrupulous in its efforts to ensure that every aspect of the marketing of "Tobacs" is consistent with this characterization and is designed to position "Tobacs" in the minds of consumers as smokeless tobacco. The following factors are significant in this regard:

- o The only difference between "Tobacs" and conventional portion-packed moist snuff products is that "Tobacs" use a masticatory carrier base instead of a tea-bag type pouch to bind and deliver the tobacco, so the product can be chewed rather than sucked.
- o "Tobacs" contain real tobacco, not abstracted nicotine or tobacco flavoring.
- o "Tobacs" are tobacco brown in color. The brown tobacco color and the 1 gram hexagon shape were deliberately selected to distinguish "Tobacs" from "chewing gum" as now marketed in the United States.
- o "Tobacs" are packaged in a cigarette style flip-top box, which is intended to foster their display in conjunction with other tobacco products and to further distinguish the product from "chewing gum."
- o "Tobacs" are sold under a tobacco brand name (Masterpiece), which is registered world-wide as a trademark for the class of tobacco products and is used by The Pinkerton Tobacco Company only for tobacco products.
- o "Tobacs" are distributed only through tobacco channels. They are labeled, distributed and intended for sale only through traditional tobacco outlets to adult tobacco users.

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- o Pinkerton goes to great lengths to assure that "Tobacs" will be sold only to adults. The Company's sales force is under explicit instructions to have "Tobacs" presented for sale only with other tobacco products and not as or among displays of candy and chewing gum. In addition, each package of "Tobacs" carries the following statement: "This tobacco product is not for use by minors." Furthermore, each carton of "Tobacs" bears an elaborate cautionary message to the retailer about the true tobacco nature of the product and against sale of the product to children. See Exhibit A. Specifically, it states in bold print:

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

- o Unlike chewing gums, "Tobacs" are never promoted for use by children. Pinkerton has a time-honored corporate policy of not advertising or promoting its smokeless tobacco products in any way that is directed at children. A copy of the Company's Advertising and Sampling Code is attached as Exhibit B.
- o In product labeling and advertising, "Tobacs" are promoted only as a convenient and discrete smoke-free tobacco alternative for use when and where smoking is not permitted and/or not appropriate.
- o "Tobacs" are subject to the federal excise tax for smokeless tobacco. See Exhibit C.

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- o "Tobacs" are governed by and comply with all aspects of the Comprehensive Smokeless Tobacco Health Education Act of 1986, including the requirements for warning labels, restricted advertising, and ingredient reporting. (See infra at 5-8.)
- o "Tobacs" are further differentiated from conventional chewing gums by both the nature of the masticatory base and the production process that is employed in their manufacture. Of course, all of the ingredients used in the "Tobacs" chewable carrier base are approved for use in food under 21 CFR § 172.615. To the best of Pinkerton's knowledge, however, the "Tobacs" base uses a formulation that is different from that used in currently marketed conventional chewing gum products. Further, "Tobacs" are manufactured using a special process that was developed specifically for this product and is not used by conventional chewing gum manufacturers.

In sum, there can be little doubt about the true nature and intended use of this tobacco product.

II. MASTERPIECE "TOBACS" ARE COMPLETELY AND EXCLUSIVELY REGULATED AS SMOKELESS TOBACCO PRODUCTS UNDER THE COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT OF 1986

A. The Comprehensive Smokeless Tobacco Health Education Act of 1986

Given the highly regulated nature of modern American society, it is rather remarkable that until last year, smokeless tobacco was not subject to particularized regulation by any federal agency. But as cigarette smoking has increasingly fallen out of favor with the American public, renewed attention has been given to the use of smokeless tobacco, and Congress was prompted to pass the Comprehensive Smokeless Tobacco Health Education Act of 1986 ("Smokeless Tobacco Act"), P.L. 99-252, 100 Stat. 30, codified at 15 U.S.C. §§ 4401 et seq.

The Smokeless Tobacco Act, which specifically sanctions the continued use and sale of smokeless tobacco, was also intended to establish certain constraints on the production and marketing of these products, as well as to "broaden our knowledge of effects of smokeless tobacco use and to make such knowledge readily

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available to the public." S. Rep. No. 209, 99th Cong., 2d Sess. 3 (1986). As its name suggests, therefore, the Comprehensive Smokeless Tobacco Health Education Act of 1986 created a comprehensive regulatory scheme covering the composition, labeling, advertising, use, and study of smokeless tobacco products.

Specifically, Section 3 of the Act (15 U.S.C. § 4402) establishes advertising restrictions and warning requirements for product labeling and advertising. Among other things, Section 3 bans all radio and television advertising for smokeless tobacco products. 15 U.S.C. § 4402(f). Section 3 also requires that one of three specific health warnings be conspicuously presented on all product packages and in all product advertisements (except on billboards). 15 U.S.C. § 4402(a). The Federal Trade Commission (FTC), which was given responsibility for the implementation and enforcement of the Act's advertising and labeling provisions, has issued regulations governing the placement, format, conspicuousness and rotation of the product warnings. 51 Fed. Reg. 40005 (November 4, 1986). Smokeless tobacco companies must not only comply with these label specifications, but must do so in accordance with a formal FTC-approved plan prepared by each company for the display and rotation of the warnings among their product labels and advertisements. 15 U.S.C. § 4402(b)-(d). In addition, each smokeless tobacco company is required to report to the FTC annually on its advertising and marketing practices, and the FTC then reports to Congress biennially on advertising and marketing practices in the industry and on its recommendations, if any, for further legislative action. 15 U.S.C. § 4407(b).

Section 4 of the Smokeless Tobacco Act (15 U.S.C. § 4403) pertains to product composition. Specifically, it requires each manufacturer of smokeless tobacco to submit an annual report to the Secretary of Health and Human Services (HHS) identifying (1) all ingredients added to tobacco in the manufacture of its smokeless tobacco products, and (2) the quantity of nicotine contained in each of its products.<sup>1/</sup> 15 U.S.C. § 4403(a). HHS is authorized to evaluate and to conduct research into health

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<sup>1/</sup> To protect the proprietary nature of this information, the statute expressly allows manufacturers to report their ingredients without reference to product or brand names and to combine their ingredients in a single composite list for submission to HHS. The statute further provides that all ingredient information reported to HHS must be held in strict confidence.

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risks associated with the use of any or all of the listed ingredients. 15 U.S.C. 4403(b)(1). HHS is invited to report periodically to Congress its findings in this regard, as well as "any other information which the Secretary determines to be in the public interest." *Id.*

Section 2 (15 U.S.C. § 4401), the third key substantive provision of the Act, directs the Secretary of HHS to design and implement a program to inform the public about the health effects of using smokeless tobacco. In particular, HHS is instructed to conduct and support research into use patterns, health effects and other issues pertaining to smokeless tobacco; to develop educational programs and publications regarding the adverse health effects of using smokeless tobacco; and to provide grants and technical assistance to the states for programs in these areas. 15 U.S.C. § 4401(a),(b). Additionally, HHS must report biennially to Congress on its efforts in these areas, including current usage of smokeless tobacco; health effects of such use and issues targeted for or in need of further research; the impact on smokeless tobacco use of public education about adverse health effects; and recommendations, if any, for further legislation. 15 U.S.C. § 4407(a).

The requirements of Sections 3 and 4 may be enforced by injunction issued by any federal district court upon application of the FTC or the Attorney General (on behalf of the FTC or HHS). 15 U.S.C. § 4405. In addition, any violation of Sections 3 and 4(a) (ingredient reporting) is considered a misdemeanor punishable by a fine of not more than \$10,000. 15 U.S.C. § 4404(a)(2).

**B. Masterpiece "Tobacs" Are Smokeless Tobacco Products  
Subject To Regulation Under The Comprehensive  
Smokeless Tobacco Health Education Act Of 1986.**

"Smokeless tobacco" is defined in Section 9 of the Smokeless Tobacco Act as: "any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity." 15 U.S.C. § 4408(1). Masterpiece "Tobacs" are made from ground tobacco, with the addition of flavors, sweeteners and a masticatory binder. As such, they are undeniably subject to the regulatory scheme established by the Smokeless Tobacco Act; indeed, we read Mr. Ronk's letter as conceding that "Tobacs" are properly subject to the terms of the Smokeless Tobacco Act.

As a responsible manufacturer of smokeless tobacco, Pinkerton has worked diligently to assure that "Tobacs" are

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marketed in conformity with all of the Act's requirements. Advertising for "Tobacs" complies with all of the Act's advertising restrictions and warning requirements. Additionally, each package and carton of "Tobacs" carries the mandated warning(s), and the Company has submitted to the FTC and received approval of its plan for the display and rotation of the required warnings on the product label. See Exhibit D. Finally, the ingredients in "Tobacs" are included in the manufacturer's confidential ingredient list, which will be submitted to HHS in accordance with Section 4, along with the necessary information on nicotine content.

C. The Comprehensive Smokeless Tobacco Health Education Act of 1986 Establishes An Exclusive Regulatory Scheme for Smokeless Tobacco Products

The sole basis for regulatory jurisdiction over a tobacco product such as Masterpiece "Tobacs" is the Smokeless Tobacco Act. It is clear from a number of factors that Congress intended the Smokeless Tobacco Act to establish a comprehensive and exclusive basis for regulating smokeless tobacco products, of which "Tobacs" are undeniably one.

1. General Principles of Statutory Construction

First, it is apparent from both the title of the Act and its breadth that Congress intended to create a comprehensive regulatory scheme specifically applicable to smokeless tobacco products which, until 1986, were largely unregulated. It is a well-established legal principle that a statute designed specifically to govern a matter or issue (such as smokeless tobacco) will take precedence over a more generally applicable statute (such as the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq.) that might also conceivably apply. Busic v. United States, 446 U.S. 398 (1980). See generally, Sand, Sutherland on Statutory Construction § 51.05 (4th Ed.).

2. Legislative Intent

In addition, the intention of Congress that the provisions of the Smokeless Tobacco Act be controlling is expressly stated in Section 7 of the Act, titled "Preemption." Section 7 explicitly prohibits any federal, state or local entity from requiring any health warning in smokeless tobacco labeling or advertising that is in addition to or different from the warnings

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required by Section 3 of the Smokeless Tobacco Act. 15 U.S.C. § 4406(a),(b). Although this preemption provision specifically addresses only health warnings in labeling and advertising, the underlying intent -- that the new comprehensive regulatory scheme for smokeless tobacco products shall prevail, even over other potentially more stringent requirements (including those that might arise under other federal statutes) -- is clear and may fairly be imbued with more general significance. The absence in Section 7 of any reference to other smokeless tobacco labeling or non-labeling issues, including product composition, is certainly not significant, because before the Smokeless Tobacco Act was passed in 1986, no other regulatory scheme, including FDA's, had ever been applied to smokeless tobacco. Congress correctly believed that these matters were not subject to scrutiny under any other statute.<sup>2/</sup>

Insofar as Congress could anticipate potential conflicts, it sought to address them explicitly. Thus, in addition to Section 7, there are two provisions in the Smokeless Tobacco Act that are specifically designed to clarify the Act's effect on and relationship to the Federal Trade Commission Act and the FTC's authority thereunder. For example, any violation of Section 3 of the Smokeless Tobacco Act or its implementing regulations is specifically and automatically deemed a violation also of Section 5 of the FTC Act (15 U.S.C. § 45), which deals with unfair or deceptive acts or practices in commerce, including product promotion and advertising. 15 U.S.C. § 4404(a). The Smokeless Tobacco Act further provides that except for the specific substantive requirements established in Section 3, nothing in the Smokeless Tobacco Act shall be construed either to restrict or to expand the FTC's authority under its organic statute to regulate the advertising of smokeless tobacco products. 15 U.S.C. § 4404(c).

Significantly, there are no comparable provisions regarding the Federal Food, Drug and Cosmetic Act (FDC Act), or any other statute administered by HHS. The obvious explanation for this discrepancy, of course, is that the FTC's jurisdiction over the promotion of all goods in commerce, including tobacco products,

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<sup>2/</sup> See, e.g., H.R. 2376 and H.R. 3294, bills that were introduced in the current session of Congress specifically to establish CPSC and FDA jurisdiction, respectively, over tobacco products.

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was well established, and Congress wanted to eliminate any potential uncertainty about how this historically recognized authority should be reconciled with the provisions of the new Smokeless Tobacco Act. In contrast, since neither HHS generally, nor FDA in particular, has any jurisdiction over tobacco products (except insofar as marketed as a drug or device) (see infra at 11-13), there was no potential conflict there for the Congress to resolve.

### 3. Practical Necessity

Even if there were no affirmative evidence of Congressional intent to establish an exclusive regulatory scheme under the Smokeless Tobacco Act, it would be necessary and consistent with well-established judicial precedent to infer such intent or to so construe the statute -- at least with respect to a product like "Tobacs" -- to avoid what would otherwise be an irreconcilable conflict with the Federal Food, Drug and Cosmetic Act. See, e.g., Brown-Forman Distillers Corp. v. Mathews, 435 F.Supp. 5 (W.D. Kentucky 1976).

In Brown-Forman, the court held the Bureau of Alcohol, Tobacco and Firearms (BATF) to have exclusive jurisdiction over the labeling of alcoholic beverages under the Federal Alcohol Administration Act of 1935, even though alcoholic beverages also qualified as "food" under the FDC Act. The holding rested in large part on significant conflicts between the labeling requirements imposed by the two statutes. The situation with "Tobacs" is even more compelling in this regard, because the labeling requirements at issue in Brown-Forman, while inconsistent, were arguably not irreconcilable. In contrast, the provisions of the FDC Act that would apply to "Tobacs" conflict with the Smokeless Tobacco Act in ways that are direct, fundamental and utterly irreconcilable.

The ingredient reporting requirement of the Smokeless Tobacco Act, for example, is specifically designed to protect the confidential and proprietary nature of that information. S. Rep. No. 209, 99th Cong., 2d Sess. 19 (1986). Thus, Section 4(a) provides that the ingredients reported to HHS need not be identified by manufacturer or brand, may be submitted anonymously, and must be handled and maintained by HHS in accordance with special rules designed to maintain confidentiality. If "Tobacs" were also subject to the food labeling requirements of the FDC Act, these confidentiality procedures would be for naught, because the FDC Act requires that

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each ingredient in a food be declared by its common or usual name on the product label. 21 U.S.C. § 343(i).

In addition, the assertion of jurisdiction over "Tobacs" under the FDC Act creates another conflict of an even more fundamental nature. The Smokeless Tobacco Act specifically sanctions the marketing of smokeless tobacco products such as "Tobacs," subject to the warning requirements and other promotional constraints imposed by the statute. Under the FDC Act, on the other hand, "Tobacs" would necessarily be banned as an adulterated food because of the presence of tobacco.

Thus, it is apparent that to give effect to the FDC Act in this case (by treating "Tobacs" as food) would render the Smokeless Tobacco Act a nullity. Such a result is not favored by the law. See, e.g., Reiter v. Sonotone Corp., 442 U.S. 330, 339 (1979); Symons v. Chrysler Corp. Loan Guarantee Board, 670 F.2d 238, 241-42 (D.C. Cir. 1981). Nor is it consistent with the standard convention in cases such as this. As described in Sutherland on Statutory Construction:

General and special acts may be in pari materia. If so, they should be construed together. Where one statute deals with a subject in general terms, and another deals with a part of the same subject in a more detailed way, the two should be harmonized if possible; but if there is any conflict, the latter will prevail, regardless of whether it was passed prior to the general statute, unless it appears that the legislature intended to make the general act controlling.

Sand, Sutherland on Statutory Construction § 51.05 (4th ed.). Accordingly, the Smokeless Tobacco Act must be recognized as the exclusive regulatory authority applicable to "Tobacs".

III. TOBACCO PRODUCTS THAT ARE INTENDED SOLELY  
TO PROVIDE TOBACCO PLEASURE ARE NOT SUBJECT  
TO REGULATION BY FDA UNDER THE FDC ACT

The Federal Food, Drug, and Cosmetic Act does not include "tobacco" in the definition of any article subject to its coverage. See generally 21 U.S.C. § 321. Furthermore, FDA has had a longstanding practice of not even attempting to assert

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authority over tobacco products that are intended solely to provide tobacco pleasure, including chewing tobacco products.

The courts, too, have recognized that tobacco products that are only intended to provide tobacco pleasure are not subject to regulation by FDA.<sup>3/</sup> Action on Smoking and Health v. Harris, 655 F.2d 236 (D.C. Cir. 1980) (affirming FDA decision not to regulate cigarettes as a "drug," notwithstanding their nicotine content). See also FTC v. Liggett & Myers Tobacco Co., 108 F. Supp. 573 (S.D.N.Y. 1952), aff'd. per curiam 203 F.2d 955 (2d Cir. 1953) (cigarettes ruled not to be a "drug" under the Federal Trade Commission Act, which includes same definition of "drug" as FDC Act).

It is also significant that the Fair Packaging and Labeling Act (FPLA), FDA's second major source of statutory authority (in addition to the FDC Act), which addresses certain aspects of the retail labeling of FDA-regulated "consumer commodit[ies]"<sup>4/</sup> explicitly excludes "any tobacco or tobacco product" from its scope. 15 U.S.C. § 1459(a)(1). It is abundantly clear that Congress intended this additional grant of retail product labeling authority, enacted in 1966, to be consistent with the product categories over which FDA already had jurisdiction under

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<sup>3/</sup> Although courts occasionally have held tobacco products to be subject to regulation under the FDC Act as "drugs", they have done so only when the products were promoted for a "drug" purpose. United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959); United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953). Such exceptional circumstances are not present in the case of Masterpiece "Tobacs," however. Pinkerton has been rigorous in designing all labels, labeling, advertising and other promotional materials to avoid any drug-related promotion. In particular, "Tobacs" are not promoted as a smoking deterrent or other means of avoiding use of tobacco. Instead, the product is promoted solely as an alternative tobacco product for current tobacco users, particularly smokers of cigarettes, cigars and pipes.

<sup>4/</sup> A "consumer commodity" is expressly defined in the FPLA to include "any food, drug, device, or cosmetic (as those terms are defined by the [FDC] Act)." 15 U.S.C. § 1459(a).

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the 1938 FDC Act (i.e., foods, drugs, devices, and cosmetics). The FPLA definitions thus confirm that Congress then understood FDA's jurisdiction as not including tobacco or any tobacco product.

Nor has the Congressional perception of this issue changed over time. Indeed, it is precisely to remedy FDA's lack of authority over tobacco and tobacco products that the current session of Congress has seen the introduction of "The Comprehensive Tobacco Health and Safety Act of 1987" (H.R. 3294), legislation specifically designed to establish FDA jurisdiction over tobacco, as such, for the first time.

IV. MASTERPIECE "TOBACS" ARE NOT "FOOD" UNDER  
THE FEDERAL FOOD, DRUG AND COSMETIC ACT

Mr. Ronk's letter of September 16, 1987 asserts that "Tobacs" are "food," on the premise that the product is "chewing gum," a term that the FDC Act includes within the "food" definition. We do not agree. In our opinion, Masterpiece "Tobacs" are not "chewing gum" (nor "food") within the meaning of the FDC Act, but simply and exclusively smokeless tobacco.

The pertinent FDC Act definition provides as follows:

The term "food" means (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.

21 U.S.C. § 321(f). (Emphasis added.) Unfortunately, there is no definition or elaboration in the FDC Act itself, or in its legislative history, of what constitutes a "chewing gum." It is fair to presume, however, that as with all FDA-regulated products, the status of "chewing gum" within the meaning of the Act turns on a variety of factors, including product composition, intended use, and other product attributes; 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. As shown below, both the legislative history of the FDC Act and FDA precedents during the nearly 50 year period since its passage support this view.

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A. The Legislative History of the FDC Act Shows That Not All Chewing Gum Products Were Intended To Be Treated As "Foods"

Senate Report No. 361 (accompanying S. 5, the bill in the 74th Congress that preceded the legislation that was eventually signed into law as the FDC Act during the 75th Congress) discusses the potential reach of the definitions of "food," "drug," and "cosmetic" in the legislation. In the course of this discussion, the following statement appears:

The use to which the product is to be put will determine the category into which it will fall. . . . The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put. For example, the manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing the article fairly and unequivocally as a drug product.

S. Rep. No. 361 (74th Cong., 1st Sess. 4, March 26, 1935).  
(Emphasis added.)

This passage dramatically illustrates the view of Congress that the mere use of a chewable carrier does not determine, nor necessarily warrant, regulation of the product at issue as a food.<sup>5/</sup> Rather, other factors may properly be regarded as controlling (e.g., drug ingredients and drug claims). Applying this concept to Masterpiece "Tobacs," it is obvious that the product is a true tobacco product which is "fairly and

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<sup>5/</sup> The courts have repeatedly recognized that Senate Report No. 361 provides authoritative legislative history concerning the scope of definitional terms appearing in the FDC Act of 1938. National Nutritional Foods Assn. v. FDA, 504 F.2d 761, 789 (2d Cir. 1974); United States v. An Article . . . Sudden Change, 409 F.2d 734, 739 (2d Cir. 1969).

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unequivocally" represented and sold for use as a tobacco product and not as a drug, or as a food or for food use.<sup>6/</sup> Therefore "Tobacs" fall outside of FDA's jurisdiction.

B. FDA Has Not Regulated All Chewable Products  
As Food

The recent assertion by the Center for Food Safety and Applied Nutrition that "Tobacs" are "chewing gum," and therefore a "food," is not consistent with the Agency's own historical precedent. FDA has itself repeatedly accepted the proposition that the mere inclusion of a masticatory base or carrier does not necessarily warrant regulating a product as "food" if the chewable base is simply used as a vehicle for some other characterizing ingredient or property that is distinctly different from that associated with a traditional chewing gum.

For example, FDA recently approved the marketing of a chewable gum product called "Nicorette" as a prescription drug. Nicorette is intended for use "as an aid to smoking cessation," an obviously therapeutic purpose. Other notable gum-based products have long been on the market as non-prescription drugs. For example: "Feen-a-Mint" laxative gum, distributed by Plough, Inc. (Physicians' Desk Reference for Non-Prescription Drugs, 1987 ed., p. 419); "Aspergum Chewing Gum," distributed by Plough, Inc. (Handbook of Non-Prescription Drugs, 8th ed. 1986, p. 210). In these instances, FDA recognized the products' therapeutic ingredients and purposes as controlling the products' regulatory classification.

In a somewhat more unusual (and also more compelling) situation, FDA several years ago permitted the marketing as a medical device of a chewing gum product that was specially

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<sup>6/</sup> Cf. Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 337 (7th Cir. 1983), aff'g 547 F. Supp. 880 (N.D. Ill. 1982); American Health Products Co., Inc. v. Hayes, 574 F. Supp. 1498, 1508 (S.D.N.Y. 1983) (in analyzing what constitutes "food" and "use for food" for purposes of determining regulatory status of "starch blockers," the courts rejected company arguments that presence of food-derived or food-related ingredients is sufficient to qualify product as "food" under FDC Act).

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formulated with abrasives to remove dental plaque. "Substantial Equivalence" Determination for Dental Chewing Gum (K 810037, April 8, 1981). Check-Up Gum is now being sold for this purpose under the medical device, and not the food, provisions of the FDC Act. Again, the product's regulatory status was deemed to turn on the nature and purpose of its characterizing abrasive ingredient, which was intended to physically remove plaque from the teeth.

Considered in light of these administrative precedents, it becomes apparent that the Center's initial conclusion regarding the regulatory status of "Tobacs" is not correct. To the contrary, it would appear that FDA's own past actions in this area support our view that the mere use of a chewable base in formulating Pinkerton's new smokeless tobacco product is not enough to convert "Tobacs" into "chewing gum" within the meaning of 21 U.S.C. § 321(f).<sup>8/</sup> "Tobacs" contain a significant amount of tobacco and are characterized by their tobacco content. Further, the composition of "Tobacs" masticatory base is not used in any conventional chewing gum of which Pinkerton is aware, and "Tobacs" are manufactured by a process that was developed specifically for this purpose and is significantly different from the process used to manufacture ordinary chewing gums. Finally, "Tobacs" are uniformly and unequivocally marketed and used as a smokeless tobacco product for adult tobacco users.

In sum, there is nothing whatsoever in the composition, nature, or marketing of "Tobacs" which suggests they are anything other than exclusively a smokeless tobacco product as that term is commonly understood. The evidence is overwhelming that the characterizing feature of "Tobacs" is their tobacco content, and the accompanying demonstrable intent of their manufacturer is to

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<sup>8/</sup> That the products cited above properly remained subject to FDA jurisdiction, while "Tobacs" would not be regulated by FDA at all, does not undercut the strength of this analysis or its applicability to "Tobacs." It is of no legal consequence that FDA would be deprived of jurisdiction over "Tobacs" if it were to determine that the product is not "chewing gum." "Tobacs will still be subject to stringent regulation under the Smokeless Tobacco Act. There is simply no legal or policy basis for FDA to alter its historical approach to such questions in this case.

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market "Tobacs" as a smokeless tobacco product. In these circumstances, there is simply no legal basis for the Center's determination to subject "Tobacs" to regulation as a "food." Indeed, it is unprecedented for the Agency to base a determination of regulatory status not on the characterizing ingredients of the product, but rather on the non-characterizing ingredients (i.e., sweeteners, flavors and binders).

C. Public Policy Considerations

It would also be contrary to sound public policy for FDA to attempt to regulate "Tobacs" as "chewing gum"/"food." As Mr. Ronk's letter of September 16, 1987 makes clear, if "Tobacs" were deemed to be a "food," the product could not be marketed at all. This would have the effect of unfairly depriving tobacco users of an alternate means of obtaining tobacco pleasure that does not subject other persons to the presence of tobacco smoke. Given the current public health concern about the alleged adverse effects of "passive smoking," "Tobacs" should be welcomed as a market innovation which provides smokers with a tobacco product they can use without exposing others to unwanted tobacco smoke.

V. CONCLUSION

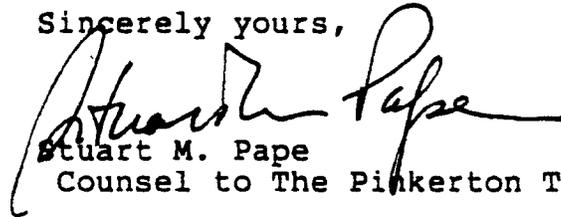
In summary, Masterpiece "Tobacs" are properly regarded and exclusively regulated as smokeless tobacco products, not as "chewing gum"/"food" within the meaning of the FDC Act. "Tobacs" are intended to provide tobacco pleasure for adult tobacco users, and they are appropriately and amply regulated under federal statutes that govern and tax such products.

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If you would find it helpful, we would be pleased to meet with you to discuss this matter, and we would be pleased to provide additional information upon request. We appreciate your consideration of this matter and look forward to your response.

Sincerely yours,



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Enclosures