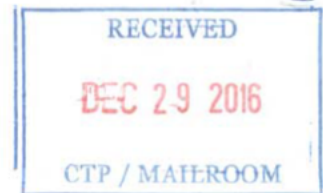


Anna Laakmann
Tel 202.533.2364
Fax 202.261.0159
laakmanna@gtlaw.com



December 28, 2016

Via Federal Express



Ann Simoneau
DPAL-WL Response, Office of Compliance and Enforcement
FDA Center for Tobacco Products
c/o Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: **Response to Warning Letter Issued to Swisher International, Inc. (RW 1600606)**

Dear Ms. Simoneau:

Swisher International, Inc. (Swisher) is submitting a response to the Warning Letter dated December 9, 2016 issued to Swisher's President, Peter Ghiloni. For the reasons set forth below, Swisher Sweets little cigar products, including without limitation the Grape product specifically addressed in your letter, are not in violation of the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and no corrective action is required.

Swisher does not sell and never has sold cigarettes. Since its founding more than 150 years ago, Swisher has been in the cigar business. Because there are evident differences between cigarettes and Swisher Sweets little cigars -- and FDA has offered no evidence to suggest that consumers do not understand that Swisher Sweets products are little cigars -- Swisher Sweets products are not cigarettes under section 900(3) of the FDCA. Accordingly, they are not subject to any of the provisions of the FDCA specifically pertaining to cigarettes, including section 907(a)(1)(A) of the FDCA.

As the FDA has acknowledged, neither the Tobacco Control Act nor its implementing regulations prohibits the manufacture and sale of flavored little cigars. *See* Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule, 81 Fed. Reg. 28974, 29055 (May 10, 2016) ("FDA is not banning flavored tobacco products with this final deeming rule."). Therefore, Swisher Sweets Grape products are not adulterated under section 902(5) of the FDCA. Furthermore, because Swisher Sweets Grape products do in fact

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have a grape flavor (and any other Swisher Sweets little cigar products labeled as having a flavor are likewise flavored consistent with the labeling), the products are not misbranded under sections 903(a)(1) and 903(a)(7)(A) of the FDCA.

The Warning Letter's reading of section 3(1) of the Federal Cigarette Labeling and Advertising Act of 1965 (CLAA), incorporated by reference in section 900(3) of the FDCA, seemingly would reclassify all little cigars as cigarettes, even though little cigars are a federally created and recognized product class wholly distinct from cigarettes. This purported reclassification is an impermissible interpretation of section 3(1) of the CLAA, which maintains a legal distinction between cigarettes and little cigars that has existed for fifty years.

Swisher Sweets Grape Products, like all products that Swisher sells, are wrapped in tobacco, so they are not "cigarettes" under section 900(3)(A) of the FDCA. Presumably, the Warning Letter takes the position that Swisher Sweets Grape products are cigarettes under section 900(3)(B) of the FDCA because they are "likely to be offered to, or purchased by, consumers as a cigarette." However, this position is untenable, because it is not supported by the facts and it is contrary to clearly established federal law governing tobacco products.

Under the FDCA, as amended by the Tobacco Control Act, three statutory criteria determine whether a product is a cigarette because it "is likely to be offered to, or purchased by, consumers as a cigarette" - the product's appearance, its filler, and its packaging and labeling. Swisher Sweets Grape products clearly fall outside the scope of this definition, because there are obvious differences between Swisher Sweets and cigarettes with respect to each of the three statutory criteria. These differences have been consistently recognized for decades by various federal statutes and regulations and federal agencies including, but not limited to, the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and, more recently, the Alcohol and Tobacco Tax and Trade Bureau (TTB). Neither the Tobacco Control Act nor its implementing regulations have altered the longstanding legal distinction between cigarettes and little cigars.

First, with respect to appearance, the focus of federal statutes governing the distinction between little cigars and cigarettes has always been on the wrapper. The typical cigarette is wrapped in white paper. By contrast, Swisher Sweets products, like all little cigars that Swisher sells, have a darkly colored brown homogenized tobacco leaf (HTL) wrapper that contains at least two-thirds tobacco consistent with federal requirements, does not have the appearance of paper, and is clearly distinguishable from a paper cigarette wrapper.

Second, with respect to filler, Swisher Sweets little cigar products, like all cigars that Swisher sells, contain tobacco that is distinctly different from cigarette tobacco. Cigarette filler tobacco consists predominantly of milder flue-cured tobacco, some light burley and some Oriental tobacco. Cigarette tobacco is cured by intense heat which dries the leaf more quickly and destroys its naturally occurring enzymes. Cigarette tobaccos are chemically more acidic and contain more sugar. The cigar filler tobacco in Swisher Sweets products, by contrast, consists of predominantly air-cured and fermented tobaccos whose characteristics are quite different from cigarette tobacco. The naturally occurring enzymes in the leaf work to reduce the sugar content. As a result, Swisher cigar tobaccos, which are chemically alkaline, have lower levels of sugar

than cigarette tobaccos. Swisher Sweets cigar products also do not contain the same additives and/or number of additives that are typically found in cigarette tobacco. These differences between cigarette tobacco filler and the tobacco filler in Swisher cigars produce a markedly different smoking experience that is readily apparent to the consumer.

Third, with respect to product packaging and labeling, ATF Ruling 73-22 sets forth the requirement that little cigar packaging “conspicuously declare it to be a cigar” and that all “marketing materials and advertising clearly present the product to the consumer as a cigar and not as a cigarette.” If a product is packaged in 20 count packages, the declaration “cigar,” “small cigar,” or “little cigars” must appear “in direct conjunction with, parallel to, and in substantially the same conspicuousness of type and background as the brand name each time the brand name appears.” In accordance with ATF Ruling 73-22 and 27 C.F.R. § 40.214, Swisher clearly informs consumers that its Swisher Sweets products are little cigars and not cigarettes. The words “little cigars” and “filtered little cigars” are prominently displayed in numerous places on the product packaging.

The definition of “cigarette” that is contained in section 3(1) of the CLAA (15 U.S.C. § 1332) and incorporated by reference in section 900(3) of the FDCA (21 U.S.C. § 387(3)) is the exact same definition that was established by the Excise Tax Reduction Act of 1965. *See* Pub. L. 89-44 (79 Stat. 136); 26 U.S.C. § 5702 (defining “cigar” and “cigarette”). The Senate Finance Committee in 1965 noted that little cigars wrapped in homogenized tobacco could be manufactured using cigarette manufacturing machinery, which would necessarily produce little cigars in the size and shape of cigarettes. Nonetheless, there was never any suggestion that these characteristics would, by themselves, transform a product into a cigarette. *See* S. Rep. No. 89-234, at 54 (1965), reprinted in 1965 U.S.C.C.A.N. 1690, 1744.

In 1973, Congress enacted the Little Cigar Act, which extended, to little cigars, the television advertising ban that previously had applied only to cigarettes. *See* Little Cigar Act of 1973, Pub. L. 93-109, 87 Stat. 352. Congress rejected a proposal of the Federal Trade Commission that would have extended the advertising ban by changing the definition of cigarettes to include little cigars. Congress instead adopted a separate definition of little cigar which expressly recognized that little cigars and cigarettes are distinct products, even though they both have filters and also have essentially the same size and shape. In so doing, Congress explained that the definition of little cigars “would encompass all rolls of tobacco, other than cigarettes, *which are the same size as cigarettes.*” S. Rep. No. 93-103, at 6 (1973), reprinted in 1973 U.S.C.C.A.N. 2040, 2044 (emphasis added).

Thus, Congress has consistently refused to classify little cigars as cigarettes merely because they are the same size and shape as cigarettes and have similar integrated filter tips. The Tobacco Control Act in no way changed this statutory classification scheme. The FDA does not have the authority to do what Congress has specifically chosen not to do by statute.

Swisher Sweets little cigars, including flavored little cigars such as the Swisher Sweets Grape product, are not cigarettes under section 900(3) of the FDCA. Accordingly, Swisher Sweets flavored little cigars are not adulterated under section 902(5) of the FDCA, because they are not

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governed by section 907(a)(1)(A) of the FDCA. They are also not misbranded under either section 903(a)(1) or section 903(a)(7)(A) of the FDCA, because the products contain a flavor consistent with their labeling.

Please contact the undersigned by phone at (202) 533-2364 or by email at laakmanna@gtlaw.com if you have any questions about this submission.

Sincerely,

A handwritten signature in blue ink, appearing to read "Anna", followed by a long horizontal flourish.

Anna Laakmann, JD
Greenberg Traurig, LLP
Counsel for Swisher International, Inc.

CENTER FOR TOBACCO PRODUCTS



MAR 23 2018

VIA UPS

Peter Ghiloni
President
Swisher International, Inc.
459 East 16th Street
Jacksonville, FL 32206

RE: Warning Letter issued to Swisher International, Inc. (RW1600606)

Dear Mr. Ghiloni:

On December 9, 2016, the United States Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) issued you a Warning Letter for the sale or distribution of flavored cigarette products in violation of section 907(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA determined that your Swisher Sweets Grape products labeled as "little cigars" meet the FD&C Act's definition of "cigarettes" and that the products were consequently either adulterated under section 902(5) of the FD&C Act, or misbranded under section 903(a)(7)(A) of the FD&C Act.

On December 28, 2016, you sent FDA a response to the Warning Letter, and we met on May 12, 2017 to discuss the Warning Letter and your response.

On August 8, 2017, you submitted Swisher's cigar warning plan, under the cigar warning statement requirements of 21 C.F.R. §1143.5. Your submission included samples of labeling and advertising with the new required warning statements for cigars.

Based on our evaluation of your new proposed labeling and advertising, it appears that once you amend your product labeling and advertising to include the required warning statements for cigars, you will have addressed the violations identified in the Warning Letter.

FDA will verify your implementation and use of the new required warning statements for cigars on your product labeling and advertising at your next inspection and will subsequently issue a close-out letter after FDA has confirmed that your products are in compliance with the FD&C Act. This letter does not relieve you or your firm from the responsibility of taking all necessary steps to ensure sustained compliance with the FD&C Act and its implementing regulations or with other relevant legal authority.

Should you have any questions or concerns, please contact Ele Ibarra-Pratt at (301) 796-9235 or by email at elenita.ibarrapratt@fda.hhs.gov.

Sincerely,

A handwritten signature in black ink that reads "Ann Simoneau".

Ann Simoneau, J.D.
Director
Office of Compliance and Enforcement
Center for Tobacco Products

VIA UPS

cc:

Christopher L. Casey
Senior Vice President & General Counsel
Swisher International, Inc.
459 E. 16th Street
Jacksonville, FL 32206

Anna Laakmann, J.D.
Greenberg Traurig, LLP
2101 L Street NW, Suite 1000
Washington, DC 20037