Cheyenne International, LLC 12/9/16

Department of Health and Human Services

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

VIA UPS and Electronic Mail

David A. Scott
Chief Executive Officer
Cheyenne International, LLC
701 S. Battleground Avenue
Grover, NC 28073
davidscott@cheyenneintl.com

WARNING LETTER

DEC 9 2016

Dear Mr. Scott:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) recently reviewed the website http://www.cheyennecigars.com,and determined that your Cheyenne products labeled as “cigars” are manufactured and offered for sale to customers in the United States. Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), these products are tobacco products because they are made or derived from tobacco and intended for human consumption. Certain tobacco products, including cigarettes, are subject to FDA jurisdiction under section 901(b) of the FD&C Act (21 U.S.C. § 387a(b)).

FDA has determined that your Cheyenne 100’s Wild Cherry products labeled as “cigars” meet

the FD&C Act's definition of "cigarettes." Section 900(3) of the FD&C Act (21 U.S.C. § 387(3)) defines the term "cigarette" as "a product that (i) is a tobacco product; and (ii) meets the definition of the term 'cigarette' in section 3(1) of the Federal Cigarette Labeling and Advertising Act," which states that the term "cigarette" means:

> (A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and (B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

Section 900(3) of the FD&C Act (21 U.S.C. § 387(3)(B)) also defines the term "cigarette" to include "tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco." Based on their overall presentation, appearance, and packaging and labeling, these products are likely to be offered to, or purchased by, consumers as a cigarette. Therefore, these products meet the definition of a cigarette in the FD&C Act.

FDA has also determined that your Cheyenne 100's Wild Cherry cigarette products are adulterated under section 902(5) of the FD&C Act (21 U.S.C. § 387b(5)) or misbranded under section 903(a)(1) of the FD&C Act (21 U.S.C. § 387c(a)(1)) or section 903(a)(7)(A) of the FD&C Act (21 U.S.C. § 387c(a)(7)(A)) because they purport to contain a natural or artificial characterizing flavor.

Flavored Cigarette Violation

FDA has determined that you sell or distribute flavored cigarette products, such as Cheyenne 100's Wild Cherry. These products are purported to contain an artificial or natural flavor that is a characterizing flavor of the products. Section 907(a)(1)(A) of the FD&C Act (21 U.S.C. § 387g(a)(1)(A)) provides:

> [A] cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice . . . that is a characterizing flavor of the tobacco product or tobacco smoke.

Cigarettes that are distributed or sold in the United States in violation of this provision are adulterated under section 902(5) of the FD&C Act (21 U.S.C. § 387b(5)). Thus, your flavored cigarette products are adulterated under section 902(5) of the FD&C Act (21 U.S.C. § 387b(5)).

If, however, these cigarette products do not contain a characterizing flavor, they are misbranded under section 903(a)(1) of the FD&C Act (21 U.S.C. § 387c(a)(1)) or section 903(a)(7)(A) of the FD&C Act (21 U.S.C. § 387c(a)(7)(A)) as their labeling or advertising is false or misleading because it makes the representation that the products contain, for example, wild cherry as a characterizing flavor of the tobacco product.

Conclusion and Requested Actions

The violations discussed in this letter do not necessarily constitute an exhaustive list. You should immediately correct the violations that are referenced above, as well as violations that are the same as or similar to those stated above, and take any necessary actions to bring your tobacco products into compliance with the FD&C Act.

It is your responsibility to ensure that your tobacco products and all related labeling and/or advertising comply with each applicable provision of the FD&C Act and FDA's implementing regulations. Failure to ensure full compliance with the FD&C Act may result in FDA initiating further action without notice, including, but not limited to, civil money penalties, no-tobacco-sale orders, criminal prosecution, seizure, and/or injunction. Please note that adulterated and misbranded tobacco products offered for import into the United States are subject to detention and refusal of admission.

Please submit a written response to this letter within 15 working days from the date of receipt describing your corrective actions, including the dates on which you discontinued the violative labeling, advertising, sale, and/or distribution of these tobacco products and your plan for maintaining compliance with the FD&C Act. If you do not believe that your products are in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. You can find the FD&C Act through links on FDA's homepage at **http://www.fda.gov (http://www.fda.gov/)**.

Please note your reference number, RW1600609, in your response, and direct your response to the following address:

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

If you have any questions about the content of this letter, please contact Ele Ibarra-Pratt at (301) 796-9235 or via email at **CTPCompliance@fda.hhs.gov (mailto:CTPCompliance@fda.hhs.gov)**.

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

cc:

Ralph Brown
Vice President, Governmental Affairs

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