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May 26, 2016

Ann Simoneau
Director, Office of Compliance and Enforcement
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Warning letters re “additive-free and “natural” claims on tobacco product labeling

Dear Ms. Simoneau:


On August 27, 2015, FDA issued warning letters to three tobacco product manufacturers – ITG Brands LLC, Santa Fe Natural Tobacco Company Inc. and Sherman’s 1400 Broadway N.Y.C. Ltd – for violations of the Food, Drug and Cosmetic Act (FD&C Act) involving their use of the descriptors “additive-free” and/or “natural,” which constitute modified risk claims made without prior FDA authorization as required by Section 911 of that statute. FDA requested that the manufacturers respond to the warning letters within 15 working days with an explanation of how they plan to remedy the violation, or to supply information showing that they are not in violation of the statute. FDA explained in its warning letters that “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, criminal prosecution, seizure, and/or injunction.”

It is now nine months since the warning letters were issued and there is no indication that the companies have taken any corrective action to remedy the violations, nor that FDA has taken any enforcement action against these continued violations. For example, Santa Fe continues to use the descriptors “100% additive-free” and “natural” in marketing its Natural American Spirit brand cigarettes and its parent company, Reynolds American, continues to cite the growth of the brand in discussing the company’s financial results with investors. During Reynolds’ February 11, 2016 4th quarter earnings call with investors, CEO Susan Cameron spoke of Santa Fe’s “excellent financial and marketplace results,” citing Natural American Spirit’s continued “double-digit” volume gains, with an increase of 18.5% for the fourth quarter. (See attachment.) Similarly, an advertisement for its Naturals brand placed by Nat Sherman in Convenience Store News, April, 2016 speaks of the “natural cigarette category” as being the “fastest growing cigarette segment,” with a 25% growth rate for the 52 weeks ending 1/2/16 according to Nielson figures. (See attachment.) Thus, months after the FDA warning letters were issued, these companies continued to aggressively promote the success of these illegal products to investors and customers.

As noted in an August 24, 2015 letter from twenty-eight public health and medical organizations to CTP Director Mitch Zeller, a significant body of research establishes the association of terms like “natural” and “additive-free” with reduced risk for tobacco products. That body of research has continued to grow since the warning letters were sent, with specific reference to the Natural American Spirit brand. A recently published study found that various pack descriptors, including

“100% Additive-Free,” along with other aspects of the American Spirit pack design, communicate lower risk to nonsmokers, former smokers and current smokers.¹ The continued and growing market presence of these products without FDA authorization, along with their aggressive promotion, pose a serious risk that people will be misled to initiate smoking, or continue smoking, by the deception that these cigarettes are less hazardous than other cigarettes. To prevent continued harm to public health, FDA must move promptly to ensure that all the products that are the subject of the warning letters are taken off the market.

Sincerely,

A handwritten signature in black ink that reads "Matthew L. Myers". The signature is written in a cursive style with a large initial "M".

Matthew L. Myers
President, Campaign for Tobacco-Free Kids

¹ Jennifer L. Pearson, et al., “American Spirit Pack Descriptors and Perceptions of Harm: A Crowdsourced Comparison of Modified Packs,” *Nicotine & Tobacco Research* 2016, 1-8 doi:10.1093/ntr/ntw097.