



August 24, 2015

Mr. Mitchell Zeller  
 Director, Center for Tobacco Products  
 U.S. Food and Drug Administration  
 10903 New Hampshire Ave.  
 Silver Spring, MD 20993

Dear Mr. Zeller:

We write to urge the Food and Drug Administration (FDA) to commence an appropriate enforcement action against Reynolds American, Inc. (Reynolds) and its subsidiary Santa Fe Natural Tobacco Co. (Santa Fe) for the marketing of Natural American Spirit brand cigarettes in violation of the modified risk provisions of the Family Smoking Prevention and Tobacco Control Act (TCA).

Section 911 of the Food, Drug & Cosmetic Act, as amended by the TCA,<sup>1</sup> prohibits the introduction of modified risk tobacco products – products sold “for use to reduce harm or the risk of tobacco-related disease” – without an FDA marketing order. That section defines “modified risk tobacco product” to mean tobacco products for which the label or advertising explicitly or implicitly represents that the product presents a lower risk of disease or is less harmful than another tobacco product, contains a reduced level of a substance, or does not contain or is free of a substance. Premarket FDA review of modified risk products is critical for the agency to determine whether the product, as used by consumers, will significantly reduce the risk of disease to individual users and to assess whether its marketing, with the claim of reduced risk, will benefit the health of the population as a whole. The potential for irreparable damage to public health from the marketing of tobacco products with modified risk claims is well illustrated by the industry’s years of deceptive advertising of “light” and “low-tar” cigarettes to

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<sup>1</sup> 21 U.S.C. §387k.

persuade health-conscious consumers to continue smoking, when in fact such cigarettes, as actually used by smokers, were no less hazardous than other cigarettes.

Recently, Reynolds' Santa Fe subsidiary launched a new national magazine advertising campaign for its Natural American Spirit brand which continues and intensifies past advertising campaigns using words and phrases such as "100% additive-free," "natural tobacco" and "organic tobacco" that imply the brand is less hazardous than other cigarettes. The new campaign includes full-page ads (some consisting of the entire back cover) in magazines such as Sports Illustrated, Glamour, InStyle, Rolling Stone, Car and Driver, Vanity Fair and US Weekly. As demonstrated by the enclosed collection of Natural American Spirit brand ads, covering the period 2000-2015, the company long has used the terms "natural tobacco," "organic tobacco" and "100% additive-free" to describe its cigarettes. However the new campaign features these descriptors much more prominently, and they easily overwhelm the small disclaimers at the bottom of the ads. There is no question that these terms imply that this brand is healthier than other brands and are understood by the public to mean a less hazardous cigarette.<sup>2</sup> Moreover, the "100% additive-free" phrase is an explicit representation that Natural American Spirit cigarettes are free of a particular substance. Therefore, because these products are being marketed with such representations, they are modified risk tobacco products, as defined in Section 911, marketed without a premarket order from FDA in contravention of the TCA.

This conclusion is not altered by the appearance of disclaimers on the products' packaging and advertising. As you are aware, the disclaimer "No additives in our tobacco does **NOT** mean a safer cigarette" is required by a Federal Trade Commission (FTC) consent order entered in 2000 to resolve

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<sup>2</sup> A significant body of research establishes the association of these terms with reduced risk. *See e.g.* Agaku, Israel T., et al., "Cigarette design and marketing features are associated with increased smoking susceptibility and perception of reduced harm among smokers in 27 EU countries," *Tobacco Control* 0:1-8, 2014 (descriptors such as "natural" or "organic" in cigarettes associated with perceptions of reduced harm among specific demographic groups); Czoli, D.D. & Hammond D., "Cigarette Packaging: Youth Perceptions of 'Natural' Cigarettes, Filter References and Contraband Tobacco," *Journal of Adolescent Health* 54:33-39, 2014 (among Canadian youth, organic and additive-free tobacco viewed as significantly more appealing and less harmful); McDaniel, P. and Malone R., "I always thought they were all pure tobacco": American smokers' perceptions of 'natural' cigarettes and tobacco industry advertising strategies," *Tobacco Control* 16:e7, 2007 (review of tobacco industry documents shows American tobacco companies have understood, for decades, that "natural" implies unwarranted health claims); Cummings, K.M., et al., "Are smokers adequately informed about the health risks of smoking and medicinal nicotine?" *Nicotine & Tobacco Research* 6(3): S333-340, 2004 (60% of adult smokers surveyed believed that removal of additives made cigarettes less dangerous to the smoker); Arnett, J.J., "Winston's 'No Additives' Campaign: 'Straight Up'?' 'No Bull'?", *Public Health Reports* 114: 522-527, 1999 (study of Winston's use of "No Additives" in advertising shows two-thirds of adolescents, and 27 percent of adults, interpret "No Additives" as an implicit health claim); Pearson, J.L., et al., "Quick, dirty, and cheap: crowdsourcing harm perceptions surrounding American Spirit Cigarette pack descriptors." 2013 Society for Research on Nicotine and Tobacco Annual Meeting, Boston, MA (in a large sample of U.S. adults, American Spirit packs with the descriptors "100% additive free" and "made with organic tobacco" were associated with reduced harm perceptions compared to a Marlboro Red pack and to the same American Spirit packs without the descriptors).

FTC charges that the use of “no additives” language in Natural American Spirit ads was deceptive in implying, without a reasonable basis, that the cigarettes are safer. A second disclaimer, “Organic tobacco does **NOT** mean a safer cigarette,” is required by an agreement entered into in 2010 with Attorneys General from 33 states and the District of Columbia to resolve charges that the use of the words “organic” or “100% organic” violated the Master Settlement Agreement by deceptively indicating that Natural American Spirit cigarettes and roll-your-own tobacco are safer than other tobacco products. As the ads enclosed with this letter make clear, Santa Fe’s use of the terms “natural tobacco,” “100% additive-free,” and “organic tobacco,” has become increasingly prominent in its advertising and now overwhelm, and render completely ineffective, the inconspicuous disclaimers on the company’s ads. The reduced risk message is further conveyed by the use of the word “natural” in the brand name “Natural American Spirit.” Thus, despite the existing disclaimers, the current ads for Natural American Spirit cigarettes convey a dominant and clear message to consumers of reduced risk and reduced exposure to harmful substances.

The misleading effect of claims that some cigarettes are “additive-free” or contain “organic tobacco” has already been recognized in a watershed federal appellate decision. When the major tobacco product manufacturers sued to have Section 911 declared unconstitutional as an infringement on freedom of speech, they argued that such claims were not misleading but simply informed consumers of factual information about their cigarettes. The U.S. Court of Appeals for the Sixth Circuit explicitly rejected plaintiffs’ claims that “marketing of tobacco products as ‘additive-free’” was designed “to appeal to naturalists and smokers who prefer organic products, even when such preferences are not linked to perceptions of health benefit.” *Discount Tobacco City and Lottery, Inc. v. U.S.*, 674 F.3d 509, 536 (6<sup>th</sup> Cir. 2012). The Court stated:

Plaintiffs have presented no evidence to suggest that “consumers who prefer organic products for environmental or other reasons . . . [but do not] perceived [them] . . . to convey a health benefit,” (*id.*), actually exist. On the contrary, we may safely presume that naturalists and those who subscribe to organic products do not engage in unmotivated or arbitrary behavior – common sense dictates the conclusion that they prefer such products precisely because they believe that natural and organic products confer health advantages over conventional products. *See Centers for Disease Control and Prevention (“CDC”), Low-Yield Cigarettes and Cigarette-Like Products*, 1 (2009) (finding that “[m]any smokers consider smoking . . . additive-free cigarettes to be safer than smoking regular cigarettes”). Consequently, Plaintiffs’ attempt to de-link hypothetical consumers’ preferences for “organic” and “additive-free products” from general health concerns is unsustainable.

*Id.*

It also is worth noting that the Natural American Spirit is experiencing significant brand growth. From 2009 to 2014, sales of Natural American Spirit cigarettes increased by 86%, while sales of all cigarettes nationally declined by 17%.<sup>3</sup> Reynolds CEO Susan Cameron, in a recent earnings call with investors, industry analysts and the media, stated that Santa Fe’s performance “continues to exceed even our own

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<sup>3</sup> Reynolds American, Inc., Filings with the U.S. Securities and Exchange Commission; U.S. Alcohol and Tobacco Tax and Trade Bureau, Tobacco Statistics, <http://www.ttb.gov/tobacco/tobacco-stats.shtml>.

high expectations,” describing the Natural American Spirit brand as “the driving force” behind Santa Fe’s success. According to Cameron, the brand had volume growth of over 25% in the second quarter of 2015, is gaining market share in every state, and has achieved “a loyal and growing franchise and the brand strength is based on its distinctive additive free style, including those made with organic tobacco.” There is every reason to believe that Natural American Spirit is growing in popularity because consumers are being misled to believe that the brand offers a healthier alternative to other cigarettes.

FDA should determine that because Natural American Spirit cigarettes are being marketed with reduced risk claims as modified risk tobacco products, as defined in Section 911, they are illegally on the market without a premarket order. It should take enforcement action against Reynolds and Santa Fe to prohibit the continued sale, without an FDA order, of products advertised or promoted with the use of the terms “natural,” “additive-free” or “organic,” or any other term or phrase conveying a message of reduced risk or reduced exposure to harmful substances, including the use of any of these terms in the brand name itself.

Respectfully submitted,

Action on Smoking & Health  
Altarum Institute Center for Prevention  
American Academy of Family Physicians  
American Academy of Otolaryngology—Head and Neck Surgery  
American Association for Respiratory Care  
American Cancer Society Cancer Action Network  
American College of Occupational and Environmental Medicine  
American Heart Association  
American Legacy Foundation  
American Lung Association  
American Psychological Association  
American Public Health Association  
American School Health Association  
American Thoracic Society  
Campaign for Tobacco-Free Kids  
Cancer Prevention and Treatment Fund  
ClearWay Minnesota  
Community Anti-Drug Coalitions of America  
Global Advisors on Smokefree Policy  
International Association for the Study of Lung Cancer  
Lung Cancer Alliance  
National Association of County & City Health Officials  
Oncology Nursing Society  
Prevention Institute  
Society for Public Health Education  
Society for Research on Nicotine and Tobacco  
Tobacco Control Legal Consortium  
Trust for America’s Health

Enclosure: Natural American Spirit Advertisements