

American Academy
of Pediatrics



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June 7, 2017

Dr. Scott Gottlieb
Commissioner
U.S. Food and Drug Administration
White Oak Building One, Room 2217
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Natural American Spirit Memorandum of Agreement

Dear Commissioner Gottlieb:

We write to urge the Food and Drug Administration not to finalize, and to reconsider, the memorandum of agreement reached with Santa Fe Natural Tobacco Company (Santa Fe) regarding its Natural American Spirit cigarettes.

On August 27, 2015, FDA issued a warning letter to Santa Fe stating that the use of the term “Natural” in the brand name Natural American Spirit, and in advertising and promotion of the brand, constituted an unauthorized modified risk claim within the meaning of section 911 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA), 21 USC 387k. The purpose of this statutory provision was to prevent cigarette manufacturers from misleading consumers into believing that their products were less hazardous than other tobacco products.¹ The modified risk provisions of the TCA were included in the statute because of a long history of misleading claims by cigarette manufacturers.

Use of the term “Natural” by Santa Fe falls squarely within the prohibition on unauthorized modified risk claims. As FDA stated in its warning letter, use of the term “Natural” “represents explicitly and/or implicitly that the products . . . present a lower risk of tobacco-related disease or are less harmful than one or more other commercially marketed tobacco products.”

¹ Pub. L. 11-31, Purposes, §§ 36-43. As noted therein, “[T]he costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injury and huge costs to our health care system.” *Id.*, at § 37.

According to a document filed publicly by Santa Fe in a United States District Court proceeding, FDA entered into a memorandum of agreement with Santa Fe's parent company or affiliate, RAI Services Company Inc., on January 19, 2017, pursuant to which Santa Fe would be permitted to continue to use the term "Natural" in the Natural American Spirit brand name and trademarks. Permitting the continued use of the term "Natural" in the brand name "Natural American Spirit" would permit Santa Fe to continue to deceive consumers into believing that its cigarettes are less harmful than other cigarettes. It also would effectively authorize the marketing of a modified risk tobacco product without compliance with the procedures and standards required by the Tobacco Control Act.

A study conducted by researchers at the Schroeder Institute for Tobacco Research and Policy Studies at Truth Initiative showed that nearly 64 percent of Natural American Spirit smokers inaccurately believe such cigarettes are less harmful, compared to only 8.3 percent of smokers of other brands who believe that their cigarettes are less harmful.² The fact that the memorandum of agreement requires Santa Fe to remove the term "natural" from its product labels, advertising and promotional materials demonstrates that FDA well knows that these terms do in fact mislead consumers. Similarly, an agreement reached by FDA with Sherman's 1400 Broadway N.Y.C. Lt., with respect to Nat Sherman cigarettes, in response to a warning letter issued by FDA on the same day as the warning letter to Santa Fe has resulted in the removal of *all* uses of the term "natural" by that company. <http://www.cspdailynews.com/category-news/tobacco/articles/5-surprising-finds-tpe-2017#page=1>. Under these circumstances, it is inexplicable and unjustifiable for FDA to permit the term "Natural" to be used in the brand name itself wherein the very name of the product misleads consumers. FDA's failure to enforce section 911 in this manner will continue to allow Santa Fe to perpetuate a deadly misrepresentation.

The memorandum of agreement is inconsistent with the requirements of the Tobacco Control Act and does not protect the public health. It is our understanding that the memorandum of agreement may still not be final; we note that the "close out date" for the Natural American Spirit warning letter is listed on the FDA website as "not issued", <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/default.htm?Page=6#wldisclaimer>. If FDA has not yet entered into a final agreement to implement the memorandum of agreement, we strongly urge the agency not do so and to take all necessary actions to ensure the removal of this misleading brand name that allows the marketing of a modified risk product

² Pearson, JL, et al., "Misperceptions of harm among Natural American Spirit smokers: results from wave 1 of the Population Assessment of Tobacco and Health (PATH) study (2013-2014)," *Tobacco Control*, published online first December 6, 2016.

without compliance with the Tobacco Control Act. If the agreement has been finalized, we urge FDA to reconsider it at once.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

cc: Mitch Zeller
Director, Center for Tobacco Products

Ann Simoneau
Director, CTP Office of Compliance and Enforcement