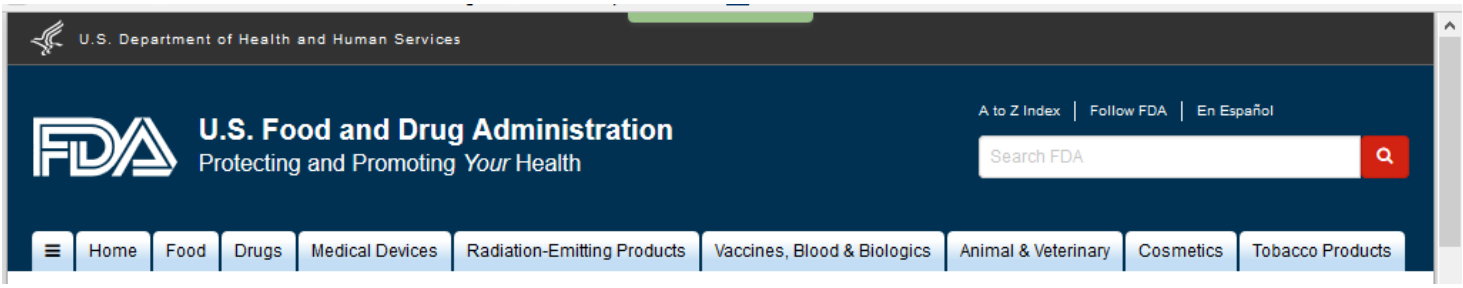

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FDA News Release

FDA takes action against three tobacco manufacturers for making “additive-free” and/or “natural” claims on cigarette labeling

For Immediate Release

August 27, 2015

Release

Today the U.S. Food and Drug Administration issued warning letters to three tobacco manufacturers — ITG Brands LLC, Santa Fe Natural Tobacco Company Inc., and Sherman’s 1400 Broadway N.Y.C. Ltd. — who describe their cigarettes on product labeling as “additive-free” and/or “natural.” The warning letters are for violations of section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The action marks the first time the FDA has used its authority under the Family Smoking Prevention and Tobacco Control Act of 2009 to pursue regulatory action regarding the use of “additive-free” or “natural” claims on tobacco product labeling.

“The FDA’s job is to ensure tobacco products are not marketed in a way that leads consumers to believe cigarettes with descriptors like 'additive-free' and 'natural' pose fewer health risks than other cigarettes, unless the claims have been scientifically supported,” said Mitch Zeller, J.D., director of the FDA’s Center for Tobacco Products. “This action is a milestone, and a reminder of how we use the tools of science-based regulation to protect the U.S. public from the harmful effects of tobacco use.”

The FD&C Act, amended by the Tobacco Control Act, gives the FDA the authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. It also created a process for the FDA to evaluate requests from companies seeking to market their products as modified risk.

Under section 911(b)(1) of the FD&C Act, a “modified risk tobacco product” is “any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.” This includes products, the label, labeling, or advertising of which represents implicitly or explicitly that the product or its smoke does not contain or is free of a substance and/or that the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products.

A manufacturer who seeks to claim that a product poses fewer risks than other tobacco products may submit a modified risk tobacco product (MRTP) application to the FDA with scientific evidence to support that claim. To date, the FDA has not issued any orders permitting the introduction of modified risk tobacco products into interstate commerce.

The companies received warning letters for the following products and their related modified risk claims:

- **ITG Brands LLC:** Products – Winston cigarettes with the MRTP claim “Additive-free”
- **Santa Fe Natural Tobacco Company Inc.:** Products – Natural American Spirit cigarettes with the MRTP claims "Natural” and “Additive-free”
- **Sherman’s 1400 Broadway N.Y.C. Ltd.:** Products – Nat Sherman cigarettes with the MRTP claim “Natural”

The FDA has determined that these products, described as “natural” and “additive-free” on their labeling, need an FDA modified risk tobacco product order before they can be legally introduced as such into interstate commerce.

The manufacturers are requested to respond to the warning letters within 15 working days and explain what actions they plan to take to remedy the violation and come into compliance with the law or, if they do not believe that they are in violation, to provide reasoning and supporting information to the FDA. Failure to obey federal tobacco law may result in the FDA initiating further action, including, but not limited to, civil money penalties, criminal prosecution, seizure, and/or injunction.

Consumers and other interested parties can report a potential tobacco-related violation of the FD&C Act by using the FDA’s Potential Tobacco Product Violation Reporting Form.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary

drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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