Santa Fe Natural Tobacco Company, Inc. 8/27/15

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Department of Health and Human Services

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

AUG 27, 2015

VIA UPS and FAX

Michael Little, President
Santa Fe Natural Tobacco Company, Inc.
1 Plaza La Prensa
Santa Fe, NM 87507

WARNING LETTER

Dear Mr. Little:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) reviewed your cigarette product labeling and determined that your cigarette products are manufactured and distributed or offered for sale to customers in the United States. Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (the 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 several of your cigarette products are adulterated under section 902(8) of the FD&C Act (21 U.S.C. § 387b(8)) because they are modified risk tobacco products sold or distributed without an FDA order in effect that permits such sale or distribution.

Modified Risk Tobacco Product Violations

You sell or distribute cigarette products the label, labeling, or advertising of which represents explicitly and/or implicitly that the products or their smoke do not contain or are free of a substance and/or that the products present a lower risk of tobacco-related disease or are less harmful than one or more other commercially marketed

tobacco products. Specifically, you sell or distribute Natural American Spirit cigarettes described in product labeling as "Natural" and "Additive Free."

A tobacco product is considered a "modified risk tobacco product" under section 911(b)(2)(A)(i) of the FD&C Act (21 U.S.C. § 387k(b)(2)(A)(i)) if its label, labeling, or advertising explicitly or implicitly represents that: (1) the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products; (2) the product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or (3) the product or its smoke does not contain or is free of a substance. Under section 911(a) of the FD&C Act (21 U.S.C. § 387k(a)), no person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product without an FDA order in effect under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)). A product that is in violation of section 911(a) of the FD&C Act (21 U.S.C. § 387k(a)) is adulterated under section 902(8) of the FD&C Act (21 U.S.C. § 387b(8)). Your product labeling for Natural American Spirit cigarettes, which uses the descriptors "Natural" and "Additive Free," represents explicitly and/or implicitly that the products or their smoke do not contain or are free of a substance and/or that the products present a lower risk of tobacco-related disease or are less harmful than one or more other commercially marketed tobacco products. As such, these products are modified risk tobacco products. Because these products are sold or distributed to customers in the United States without an appropriate FDA order in effect under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)), these products are adulterated under section 902(8) of the FD&C Act (21 U.S.C. § 387b(8)).

FDA recognizes that Santa Fe Natural Tobacco Company, Inc. has entered into a consent order with the Federal Trade Commission (FTC) regarding the company's use of additive free claims in tobacco product advertising (Federal Trade Commission, *In the Matter of Santa Fe Natural Tobacco Company, Inc., a corporation*, Docket No. C-3952, Decision and Order, Issued June 12, 2000). This order requires, in part, that the company display certain disclosures (e.g., "No additives in our tobacco does NOT mean safer") in any advertisements using claims that represent tobacco products as having no additives, unless the company possesses and relies upon competent and reliable scientific evidence demonstrating that such products pose materially lower health risks than other tobacco products of the same type. This consent order predates the Tobacco Control Act, which was enacted on June 22, 2009 and gave FDA authority to regulate the manufacture, sale, distribution, and promotion of tobacco products, including authority over modified risk tobacco products under Section 911 of the FD&C Act (21 U.S.C. § 387k). As noted above, under section 911(a) of the FD&C Act (21 U.S.C. § 387k(a)), no person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product without an FDA order in effect under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)). Because you sell or distribute modified risk tobacco products without an appropriate FDA order in effect under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)), you are in violation of the FD&C Act, notwithstanding your consent order with FTC.

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, 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 promotion, 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.

Please note your reference number, RW1500345, 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.

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

VIA UPS and FAX

cc:

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