

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

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R.J. REYNOLDS TOBACCO COMPANY,  
LORILLARD TOBACCO COMPANY,  
COMMONWEALTH BRANDS, INC.,  
LIGGETT GROUP LLC, and SANTA FE  
NATURAL TOBACCO COMPANY, INC.,

CIVIL ACTION NO. \_\_\_\_\_

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG  
ADMINISTRATION, MARGARET  
HAMBURG, Commissioner of the United  
States Food and Drug Administration; and  
KATHLEEN SEBELIUS, Secretary of the  
United States Department of Health and  
Human Services,

\_\_\_\_\_  
Defendants.

**DECLARATION OF DAVID D. DEPALMA**

I, David D. Depalma, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

**Introduction & Issues to be Addressed**

1. I am the Senior Director of Marketing and Creative at Santa Fe Natural Tobacco Company, Inc. ("SFNTC"). SFNTC is a wholly-owned subsidiary of Reynolds American Inc. SFNTC is a tobacco manufacturer in the United States and sells its cigarettes and roll-your-own tobacco nationwide under the Natural American Spirit brand name.

2. In my current position, which I have held since June, 2007, I have responsibility for the marketing of Natural American Spirit tobacco products to consumers, including overall

brand strategic planning, advertising, and marketing communications with consumers, including packaging and point of sale marketing at retail.

3. I have been employed by SFNTC since 1997 to the present. During the course of my employment at SFNTC, I have held various positions related to the marketing of Natural American Spirit products. I started my career with SFNTC as an Associate Manager of Design, and over the years was promoted to Creative Director, Marketing Director, and currently hold the position of Senior Director of Marketing and Creative. I have a Bachelor of Fine Arts in Design from William Paterson College.

4. This declaration will address the steps SFNTC must take to comply with the new labeling requirements imposed by the Food and Drug Administration (“FDA”) in its Final Rule implementing the Family Smoking Prevention and Tobacco Control Act, Pub. Law No. 111-31, 123 Stat. 1776 (2009) (the “Act”). *See Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36628 (June 22, 2011) (“the Rule”). In particular, the declaration describes each step SFNTC must take, the cost of each step, and the timeline SFNTC will follow, in order to meet the Rule’s September 22, 2012 effective date.

#### **SFNTC’s Implementation of Packaging Changes**

5. The Rule requires that SFNTC revise the packaging for each of its 15 cigarette products. These products are packaged in individual packs, cartons, and cases. As a result, SFNTC will need to overhaul 30 distinct package designs.

6. The Rule’s labeling requirements will apply to any cigarette packaging manufactured on or after September 22, 2012, and any cigarette packaging introduced into commerce on or after October 22, 2012.

7. In order to meet the September 22, 2012 and October 22, 2012 effective dates, SFNTC has taken or plans to take the following steps:

8. First, a graphics design firm has been hired to assist SFNTC's internal creative department in designing the new labeling beginning in August, 2011. The designers are working to revise current package designs in light of the Rule's requirement that SFNTC's own branding and marketing be limited to the bottom half of both the front and the back of the package. SFNTC estimates that the cost of this graphic design to SFNTC will be approximately \$56,690 and will be incurred from August through December, 2011.

9. Second, SFNTC will need to begin the internal approval process for the new package designs in September, 2011. The approval process will be extensive given the nature of the label changes and the number of individual designs. Numerous departments—including, Consumer Marketing, Legal, Manufacturing, Operations, Procurement, Tax, and Trade Marketing—will need to perform this review.

10. Third, SFNTC will need to purchase additional printing plates and blank metal printing cylinders, which will be engraved and used to apply the ink on the new cigarette packaging. SFNTC estimates that these plates and cylinders will cost approximately \$138,860 and will be purchased in February, 2012.

11. Fourth, SFNTC will have to contract with its third-party design firm to engrave the additional printing cylinders with the new packaging designs beginning in March and April, 2012. The cost of this engraving will be approximately \$210,000.

12. Based on its best estimates, SFNTC will need to incur the foregoing costs of over \$400,000 and devote a significant number of employee hours to implementing the Rule according to the above timeline unless the effective dates of the Regulation, along with the

related labeling changes tied to the effective date of the Regulation, are postponed so that SFNTC may begin this implementation process after the conclusion of judicial review.

13. Absent a postponement, SFNTC will have no choice other than to continue with its implementation even if the District Court were to invalidate the Regulation, as it could not risk the possibility of noncompliance should the District Court reject its challenge, or should the District Court invalidate the regulation but be reversed on appeal.



David D. Depalma