

January 31, 2012

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VIA Electronic Submission

Division of Dockets Management (HFA – 305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Docket No. FDA-2011-N-0493; RIN: 0910-AG40

To Whom It May Concern:

The American Legacy Foundation appreciates the opportunity to comment on the Notice of Proposed Rulemaking regarding the Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents. Legacy files these comments in strong opposition to the proposed rule.

Legacy is dedicated to building a world where young people reject tobacco and anyone can quit. Located in Washington, D.C., Legacy develops programs that address the health effects of tobacco use, including **truth**<sup>®</sup>, an award-winning youth smoking prevention campaign, and **EX**<sup>®</sup>, an innovative tobacco cessation program. Legacy also conducts research exploring the causes, consequences and approaches to reducing tobacco use and operates a nationally-renowned program of outreach to priority populations who disproportionately bear the toll of tobacco. Legacy was created as a result of the 1998 Master Settlement Agreement (MSA) between the states and the tobacco industry. Pursuant to the terms of the MSA, Legacy cannot lobby, and therefore took no position on the Family Smoking Prevention and Tobacco Control Act as it made its way through the legislative process.

FDA issued a proposed rule that would (1) change the effective date of a provision of the Final Rule to permit the manufacturer of a cigarette or smokeless tobacco product with a trade or



brand name that is also the trade or brand name of a nontobacco product to continue to use the name if the tobacco product was sold in the United States on or before June 22, 2009; (2) permit that a manufacturer of a cigarette or smokeless tobacco product may continue to use its trade or brand name even if that name is subsequently registered with the United States Patent and Trademark Office or subsequently used for a non-tobacco product; and (3) permit such manufacturer to request an exemption that the trade or brand name registered for a nontobacco product does not have a substantial appeal to children or adolescents.

Legacy objects to the proposal on the following grounds:

1. The FDA's proposal to modify the "grandfather" date goes against Congress' specific intent and is not supported by any public health policy. The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) requires the FDA to promulgate a rule "identical" to the "Final rule" published by the Secretary of Health and Human Services in the August 28, 1996 issue of the Federal Register (Final Rule), subject only to a few specifically enumerated exceptions. These enumerated exceptions did not include changing the grandfather date in the original rule—a date that was in the public record and well known to a Congress which demonstrated that it was perfectly capable of mandating other changes to the Rule. The FDA suggests that the proposed change in the grandfather date would place the regulation in line with the original intent of the Final Rule which was to impose a prospective requirement. However, the FDA's actions today must be guided by Congress' intent in enacting the Tobacco Control Act and not what the FDA may have viewed as appropriate over fourteen years ago in a dramatically different tobacco control environment. Indeed, in determining *not* to direct the FDA to revisit the grandfather date, it is most likely that Congress recognized that manufacturers have been aware since 1996 that cross-branding tobacco and non-tobacco products is a disfavored policy. As a result, equities that may have applied to support a prospective-only requirement in connection with the 1996 Rule do not apply today. This conclusion is buttressed by the fact that in enacting the Tobacco Control Act Congress was also aware that tobacco manufacturers party to the Master Settlement Agreement have functioned under a similar provision since 1998.

The FDA's expressed concern over the manufacturers of the 17 identified cigarette and smokeless tobacco products that would apparently be required to re-brand their products, fails to present anything approaching an adequate justification for this proposal. Notably, the FDA's analysis does not even try to address how this change would serve the over-arching public health purpose of the Act. The simple answer, of course, is that it does not. Facilitating the cross-branding of tobacco and non-tobacco products only serves the interests of the affected

manufacturers in marketing their products. Indeed, FDA lists as a benefit of the rule that consumers of the affected products would not have to switch to other brands. At the same time, according to FDA's analysis, "given the addictive nature of tobacco and the lack of strong brand imagery associated with the affected products, brand loyalty is unlikely to be a primary factor in the continuance of tobacco consumption by established users of these products." While it may be true that there is little brand loyalty to these products, by the same token, there is no evidence that in enforcing the Final Rule as written, established users would be any less likely to use a new brand of the affected products as they would to switch brands. Regardless, the concern with whether consumers will or will not switch brands is not the charge of FDA. Protecting the public health is. These products, like all tobacco products, contribute to the leading cause of preventable death in the United States.

2. The limitation of the prohibition of cross-branding to trade or brand names registered with the U.S. Patent and Trademark Office (PTO) on the date the tobacco product was first sold in the U.S. ignores the fact that many trade and brand names are not registered with the PTO but nonetheless are actively used in commerce and benefit from a variety of legal protections. Not only do PTO registrations include only a subset of trade and brand names used in commerce, users of trade and brand names are well aware of this fact and have long adjusted their intellectual property programs to account for it. There are numerous easily available mechanisms for a manufacturer to determine whether a trade or brand name is already in use. These range from commercially available trademark search services to the use of Google and other internet search engines. Accordingly, if the purpose of the proposed amendment is to somehow ease the burden on manufacturers – and further assuming for the sake of argument that is a cognizable purpose under the Act – limiting the prohibition to brands registered with the Patent and Trademark Office is a "solution" to a problem that does not exist. If the purpose is to facilitate FDA's enforcement of the provision, it is equally a solution in search of a problem since the FDA has as easily accessible to it all of the many available tools to monitor the use of trade and brand names in commerce. Not only does the proposed amendment ignore how owners of intellectual property routinely protect their rights, it creates the very real possibility that trade and brand names used in commerce in connection with non-tobacco brands may also be used for tobacco brands. This would undermine the precise purpose of the underlying rule.
3. Creating a new exemption process for brands which do not have a "substantial appeal to children or adolescents" creates an opportunity for cross-branding of tobacco products under an ill-defined standard in the complete absence of any showing of any need for such exception



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or consideration of such an exception's public health impact. Moreover, we are puzzled and concerned as to why FDA would voluntarily create a new administrative burden for itself when it has so much yet to do to enforce numerous specific provisions of the Act.

As an organization whose flagship program to prevent youth smoking is based on creating a brand that competes with the tobacco companies' brands, Legacy fully understands the power of branding. In the proposed rule, FDA correctly pointed out that there is significant evidence of the power of brands. In particular, the tobacco industry has invested billions annually for marketing and advertising of its brands. That investment has paid off – the tobacco industry has some of the strongest brands in the world and they aggressively use that brand power to their advantage. Allowing any exceptions to this provision not only goes against the intent of Congress, it is a naive approach to dealing with an industry that has for years used the power of brands to entice youth and addict them to their deadly products.

For all these reasons, the American Legacy Foundation respectfully submits that the proposed changes to the Final Rule should be rejected and the proposed rule should not be promulgated.

Sincerely,

David Dobbins  
Chief Operating Officer