FDA ALERT

9/28/15

FDA Issues Proposed Rule Clarifying When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices or Combination Products

By Craig A. Koenigs, Partner

The Food and Drug Administration (FDA) has issued a proposed rule seeking to clarify the circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product under the Federal Food, Drug, and Cosmetic Act (FD&C Act). 80 Fed. Reg. 57756-57765 (September 25, 2015).

The FDA was given authority to regulate tobacco products pursuant to the Family Smoking Prevention and Tobacco Control Act, which amended the FD&C Act. The term "tobacco product" is defined under the FD&C Act as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." However, the definition excludes any article that is a drug, device or combination product. The FDA believes there is ambiguity surrounding the public's understanding of the circumstances under which a product made or derived from tobacco would be regulated as a tobacco product and when it would be regulated as a drug, device or combination product. Therefore, the FDA is proposing the addition of a new section 1100.5 to the regulations to clarify its interpretation of the drug and device definitions related to products made or derived from tobacco products. The proposed section titled "Exclusion from tobacco regulation" would read as follows:

> If a product made or derived from tobacco that is intended for human consumption is intended for use for any of the purposes described in paragraph (a) or (b) of this section, the product is not a tobacco product as defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act and will be subject to regulation as a drug, device, or combination product.
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> (a) The product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, including use in smoking cessation, the cure or treatment of nicotine addiction, relapse prevention, relief of nicotine withdrawal symptoms, or prevention or mitigation of disease;
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> (b) The product is intended to affect the structure or any function of the body in any way that is different from effects related to nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000.

In addition, the FDA is proposing to amend the existing "intended use" regulations of 21 C.F.R. §§201.128 and 801.4, by inserting a reference to the proposed rule to clarify the interplay between the regulations and the proposed rule and to conform these provisions to reflect the FDA's current application of these provisions to drugs and devices.

Comments to the proposed rule must be submitted by **November 24, 2015**.

Please contact **Craig A. Koenigs** for further information on this Alert or if you would like assistance in preparing comments or responding to the proposed rule.

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