ROETZEL
FOCUSED ON WHAT MATTERS TO YOU

FDA ALERT

7/2/15

FDA Issues Advance Notice of Proposed Rulemaking Regarding Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, E-Liquids and Novel Tobacco Products

By Craig A. Koenigs, Partner

The Food and Drug Administration (FDA) has issued an advance notice of proposed rulemaking (ANPRM) seeking comments, data, research results, or other information to inform the agency's thinking about options for issuing potential regulations related to requiring nicotine exposure warnings and/or child-resistant packaging for liquid nicotine and nicotine-containing e-liquids that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels and drinks. 80 Fed. Reg. 37555-37559 (July 1, 2015).

The ANPRM was prompted by the FDA's independent review of data and science related to the risks from accidental exposure to nicotine, including liquid nicotine and e-liquids; requests for increased regulation and controls over liquid nicotine and e-liquids received in comments to the FDA's proposed tobacco "Deeming Regulations;" and, increased public health concerns over the rise in calls and visits to poison control centers and emergency rooms related to liquid nicotine poisoning and exposure. The ANPRM sets forth a series of questions for which it seeks comments related to three subject matter areas: nicotine exposure warnings, child-resistant packaging, and other actions and considerations. The purpose or goal of commenting on an ANPRM is to assist the agency to develop and improve the drafting of proposed rules or to recommend against issuing proposed rules.

Comments to the ANPRM must be submitted by **August 31, 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 ANPRM.

Craig A. Koenigs
Partner, Roetzel & Andress LPA
1300 Pennsylvania Avenue, Suite 700
Washington, D.C. 20004
202.216.8317 | ckoenigs@ralaw.com