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RJO Update: Retail Industry Trade Regulation

April 2014

FDA Proposes Regulations for Electronic Cigarettes and Other Tobacco Products

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On April 24, 2014, the FDA proposed new regulation that would extend its authority to electronic cigarettes and other tobacco products that had previously not been covered under the Food Drug and Cosmetic Act (“FDCA”). In particular, the proposed rules would establish FDA oversight of electronic cigarettes (aka e-cigarettes), most cigars, pipe tobacco, nicotine gels, waterpipe tobacco and dissolvables not currently under the FDA’s authority. These products are newly deemed to meet the definition of “tobacco products” under the FDCA because they are made or derived from tobacco and intended for human consumption. The FDA is expected to issue the final rule establishing oversight of these newly deemed tobacco products during the upcoming months, depending on the extent of feedback received during the 75-day public comment period. The final rule would be effective 30 days after the date of publication, although the agency has prescribed periods of up to two years for manufacturers to comply with certain requirements such as labeling content.

Retailer Obligations

If enacted, the final rule would ban sales of e-cigarettes and the other newly deemed tobacco products to minors. A ban on internet sales to minors, which is already in place for cigarettes, would extend to e-cigarettes and cigars (although one option proposed by the FDA would exempt premium cigars from regulation). To ensure that e-cigarettes are not sold to minors, retailers will be required to verify, by means of photographic identification containing the bearer’s date of birth, that the person purchasing the product is not younger than 18 years of age. In addition, retailers would not be allowed to sell e-cigarettes and the other covered tobacco products through vending machines or any other mechanical device except in facilities where minors are not permitted to enter. Retailers will not be allowed to advertise e-cigarettes and the other newly deemed tobacco products, except for cigars, unless the advertisement contains a required warning statement that occupies at least 20 percent of the advertisement.

Manufacturer Obligations

Manufacturers of e-cigarettes face a host of obligations under the final rule. For example, producers will have to register with the FDA, obtain approval for their products, provide the agency with a detailed accounting of their products’ ingredients and disclose their manufacturing processes and scientific data. Producers would also be subject to FDA

inspections, and companies would no longer be able to offer free samples. E-cigarettes and other tobacco products (except for cigars, for which different warnings are proposed) will require warning labels stating that they contain nicotine, which is addictive. Manufacturers will not be allowed to advertise these products unless the advertisement bears the warning statement, which must occupy at least 20 percent of the advertisement. Moreover, manufacturers may only make implied and direct claims of reduced risk from smoking e-cigarettes or the other newly deemed tobacco products if the FDA confirms that scientific evidence supports the claim(s) and that marketing the product will benefit public health as a whole.

State Regulation

A final rule is not expected for months, and in the meantime, retailers must continue to abide by state and local bans on the sale of e-cigarettes to minors as well as other laws concerning the sale of e-cigarettes. Among many other jurisdictions, the states of California, New Jersey, Colorado and the counties of Spokane and Tacoma in Washington State already ban the sale of e-cigarettes to minors. Moreover, as of February 2014, legislation pertaining to e-cigarettes was pending in at least 28 states. One of these pending bills, California's AB 1500, would prohibit online tobacco and e-cigarette sellers from shipping their products to any California address unless they acquire a tobacco retail license. Given the extent of pending legislation related to e-cigarettes, retailers will have to monitor enactment of state legislation, which may predate publication of the FDA's final rule.

Conclusion

Retailers of e-cigarettes in several states including California must already comply with bans on sales to minors. The FDA's proposed rule, if enacted, would prohibit retailers from selling e-cigarettes and other products to minors nationwide. Although a final rule is not expected for months and may undergo revisions from the proposed version, retailers and manufacturers of e-cigarettes, non-premium cigars, nicotine gels, pipe tobacco and waterpipe tobacco should expect the FDA to ban sales to minors and require identification checks and warning requirements on packages and advertisements. In addition, attempts to portray e-cigarettes or any of the other products as safer alternatives to cigarette smoking will require approval from the FDA or risk allegations of misbranding under the FDCA. As FDA approval of the newly deemed tobacco products will likely be required, the largest manufacturers, who are most financially able to comply with the FDA rule, will likely gain market presence.

How We Can Help Your Company

Rogers Joseph O'Donnell has assisted many retail clients in complying with applicable State and Federal regulations. If you have questions about the proposed regulations and the impact of the final rule, including different compliance dates for various provisions or the warning and identification requirements, Renee D. Wasserman (rwasserman@rjo.com), Alexis J. Morris (amorris@rjo.com) and Suhani Kamdar (skamdar@rjo.com) are available to assist with any such matters. Biographies and contact information are available at www.rjo.com.

The content of this article is intended to provide a general guide to the subject matter, and is not a substitute for legal advice in specific circumstances.