MACKRELL INTERNATIONAL'S REGULATORY SUBGROUP PRESENTS

OCTOBER 2012 VOLUME 2, ISSUE 2

REGULATORY MATTERS!

FDA Regulation of Tobacco Products Set to Expand

Nearly a decade after the U.S. Supreme Court determined in *Food and Drug Administration (FDA) v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120 (2000), that the FDA did not have jurisdiction over tobacco products under the Federal Food, Drug and Cosmetic Act (FFDCA), on June 12, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) became law, and amended the FFDCA to give the Agency authority to regulate the manufacture, labeling, distribution, and marketing of tobacco products in the United States. Specifically, although a "tobacco product" is defined broadly, in pertinent part, as "any product made or derived from tobacco that is intended for human consumption," the law only provides FDA with authority to regulate, through the its new Center for Tobacco Products (CTP), cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. Any "other tobacco products" become subject to regulation only after FDA deems such products to be subject to the new law. To read more, please **click here**.

This issue of "Regulatory Matters" was written by **Azim Chowdhury**, an attorney at Keller and Heckman LLP who advises domestic and foreign corporations in matters of FDA and international regulatory compliance. To read more about Mr. Chowdhury, please **click here**.

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FDA Regulation of Tobacco Products

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Regulatory Requirements for Tobacco Companies

Due to the inherent dangers associated with their use, tobacco products are innately different from other FDA-regulated products, such as food, drugs and medical devices, which are designed to be safe and effective. How FDA should approach the task of addressing a public health crisis (*i.e.*, smoking) that claims 443,000 American lives a year, while balancing the rights of manufacturers and consumers, is a controversial topic. Against this backdrop, the Tobacco Control Act imposes a plethora of new regulatory requirements for manufacturers and importers of regulated tobacco products including, among other things, the requirement to: (1) obtain FDA pre-market review before introducing into interstate commerce any new tobacco product that was not on the market prior to, or that has been modified in any way after, February 15, 2007; (2) disclose to the Agency all ingredients, additives, and harmful and potentially harmful constituents present in the tobacco products; (3) submit to FDA all documents developed that relate to the health and toxicology of the tobacco products and their constituents, ingredients, etc.; (4) register all domestic manufacturing facilities; (5) use Good Manufacturing Practices; and (6) obtain marketing authorization from FDA prior to making any 'modified risk' claims. In general, tobacco companies that violate provisions of the Tobacco Control Act will be committing "prohibited acts," which are subject to misdemeanor and potentially felony penalties under Sections 301 and 302 of the FFDCA.

Other Tobacco Products

FDA has stated its intent to expand its authority to include currently unregulated "other" tobacco products. As noted above, the Tobacco Control Act provides that the Agency may deem by regulation that other (non-listed) tobacco products are subject to the law. This regulation, once promulgated, will likely capture cigars and pipe tobacco, as well as novel tobacco products, such as electronic cigarettes and dissolvable tobacco. FDA initially stated in an August 25, 2011 letter to stakeholders that other tobacco products captured by its "deeming" regulation "would be subject to general controls, such as registration, product listing, ingredient listing, good manufacturing practice requirements, user fees for certain products, and the adulteration and misbranding provisions, as well as to the premarket review requirements for 'new tobacco products' and 'modified risk tobacco products.'"[1] Since this letter was published, however, FDA has, for the most part, avoided making public announcements about when it expects to propose the new regulation.[2] The Agency has acknowledged that one reason for the delay is that drafting the regulation has turned out to be more complicated than expected.[3]

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FDA Regulation of Tobacco Products

Even if FDA does propose its deeming regulation this year, it could take some time before such regulation is actually implemented. First, FDA will have to get the draft regulation approved by the White House Office of Management and Budget (OMB), then publish a "Notice of Proposed Rulemaking," in the Federal Register and allow for a public comment period (usually 60 days), and then issue a final rule, which must include FDA's analysis of all the comments received. Based on the CTP's and OMB's current backlog, and the reality of election year politics, this process can be expected to take several months or even years.

Nevertheless, it is important for manufacturers and importers of cigars, pipe tobacco, electronic cigarettes, and other novel tobacco products to be prepared to comment on FDA's new deeming rule as soon as it is promulgated, as well as to prepare to be subject to FDA's regulatory requirements.

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[1] *See* FDA's August 25, 2011 letter to stakeholders, *Regulation of E-Cigarettes and Other Tobacco Products*, available online at: http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm.

[2] We note that in May 2012, the Agency announced on the Federal Business Opportunities (FBO) website that it "expects to issue a deeming regulation in summer 2012 to cover other tobacco products." No such regulation, however, was issued. *See* FDA Solicitation No. 12-223-SOL-00089, available online at https://www.fbo.gov/?s=opportunity&mode=form&id=e67b8cae5128a81ed6d50059f54372a4&tab=core&_cview=1.

[3] *See* the CTP Director Dr. Lawrence Deyton's comments at the Food and Drug Law Institute's annual conference in April 2012.

About the Author

Azim Chowdhury joined Keller and Heckman in 2010. In his role, Mr. Chowdhury advises domestic and foreign corporations in matters of FDA and international regulatory compliance. In particular, he assists corporations in establishing clearances for food and drug additives in the U.S., Canada, and European Union, with an emphasis on indirect additives used in food-contact materials. Mr. Chowdhury has also developed expertise in tobacco product regulation and has experience representing drug, dietary supplement, medical device and tobacco companies in FDA regulatory matters. He is also a frequent contributor to the Food and Drug Law Institute's (FDLI) *Update* magazine, currently serves on the Editorial Advisory Board of the *Food and Drug Law Journal*, and edited and co-authored FDLI's first tobacco-exclusive publication, *Tobacco Regulation and Compliance: An Essential Resource*.

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