

## Planning For The FDA's 'Deeming Rule' For E- Cigarettes



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2009 Family Smoking  
Prevention and

Tobacco Control Act (TCA)[1] gave the U.S. Food and Drug Administration the authority to oversee the manufacture, distribution and marketing of certain tobacco products, such as cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco and any other tobacco products that the FDA, by regulation, deems to be subject to the law. Pursuant to this authority, the FDA issued a proposed rule in April 2014 (the "Deeming Rule") that would deem electronic cigarettes containing nicotine to meet the statutory definition of a "tobacco product," thereby extending the FDA's regulatory authority to these products.[2] Among other things, the Deeming Rule would require e-cigarette companies to register with the FDA, report product and ingredient listings and obtain FDA premarket approval of new tobacco products. The FDA closed the public comment period for the Deeming Rule on Aug. 8, 2014, after receiving over 135,000 comments from members of industry, individuals, government entities and the public health community.[3] Given that there is no statutory deadline for the FDA to issue a final rule, it is difficult to predict when the Deeming Rule will be finalized; however, members of Congress have been urging the FDA to expedite its review and finalization.[4] If the Deeming Rule is finalized in its

current form, e-cigarette companies will have a period of 24 months from the date the Deeming Rule is finalized to achieve compliance. However, given the potentially onerous and costly nature of manufacturing and testing requirements, firms should start planning for compliance now to minimize the risk of the requirements causing delay or interference with business operations.

### Current Regulatory Framework for Tobacco Products

The TCA gave the FDA the authority to protect the public health by issuing regulations for tobacco product retailers, manufacturers, importers and distributors. The FDA has already issued a number of regulations for conventional cigarette, tobacco, smokeless tobacco and roll-your-own tobacco manufacturers. These regulations include requirements for establishment registration, product listing, ingredient reporting, FDA inspections, packaging, labeling and advertising and marketing authorizations for new and modified risk tobacco products. The FDA currently monitors the tobacco industry's compliance with these requirements through surveillance, inspections and investigations and can take various enforcement actions to address violations, ranging from untitled and warning letters to civil money penalty complaints, seizures, injunctions and even criminal prosecution.

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### Current Good Manufacturing Practice Regulations

The FDA has promulgated sets of current good manufacturing practice regulations, or cGMPs, for various products, including medical devices, drugs and food products, that require companies to implement systems to ensure adequate product design and control. Existing cGMP regulations for drug, medical device and food products are intentionally ambiguous to allow flexibility in implementation. Thus, the FDA largely leaves it up to manufacturers to “fill in the blanks” for the detailed requirements in company standard operating procedures. These detailed requirements should be based on various considerations, such as the product profile, risk assessment, intended use, potential safety risks to the end user, the product’s role in the supply chain (such as whether it is a component or a finished product) and the state of the technology supporting manufacturing and testing operations.

While the FDA has not yet established good manufacturing practice regulations for tobacco products, the agency can rely on existing statutes (such as the Food, Drug and Cosmetic Act, or FDCA) and other tools in its regulatory arsenal to prohibit adulterated and misbranded products from entering interstate commerce. Also, section 906(e) of the TCA provides in relevant part as follows:

In applying *manufacturing restrictions* to tobacco, the secretary shall, in accordance with subparagraph (B), prescribe regulations (*which may differ based on the type of tobacco product involved*) requiring that the *methods* used in, and the *facilities and controls* used for, the manufacture, preproduction *design validation* (including a process to assess the performance of a tobacco product), packing and storage of a tobacco product conform to *current good manufacturing practice* or *hazard analysis and critical control point methodology*, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this chapter. ... (emphasis added).

Thus, it is apparent that Congress intends for the FDA to eventually issue cGMP regulations for “deemed” tobacco products such as e-cigarettes and that such regulations may vary based on product attributes and safety profile. This “someday” for the FDA’s promulgation of cGMP regulations may be fast approaching, particularly as the FDA faces increased pressure from public health authorities, Congress and the public to safeguard the public health by regulating this largely unregulated product and requiring e-cigarettes to be manufactured in a way that assures product consistency, safety and quality. The next question, then, is once e-cigarettes are “deemed” to be tobacco products falling under the FDA’s regulatory jurisdiction, how can firms

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manufacture, test, label and market these products in compliance with good manufacturing practices? Although it is challenging to predict the FDA's approach for tobacco GMPs, firms can get a start on cGMP compliance by using cGMP requirements for other products under the FDA's regulatory authority as guidelines for foundational requirements until the FDA finalizes the Deeming Rule and issues more specific regulations and/or guidance documents. We discuss some of these general principles below.

### **Manufacturing and Testing Controls**

As companies in other industries regulated by the FDA, such as drug and medical device firms, can attest, a solid technical and scientific understanding of every product line and the various procedures used to manufacture and test each product is a prerequisite for the development of a strong and comprehensive cGMP compliance program. Interestingly, the TCA specifically mentions "hazard analysis and critical control point methodology" (HACCP) in reference to tobacco GMPs. Because of the analytical and mechanical complexity of e-cigarettes and the fact that e-cigarettes actually represent a combination of different products (i.e., nicotine is a plant-derived chemical whereas the electronic nicotine delivery system is mechanical in nature), e-cigarette firms will need to understand the unique chemical, technical and toxicological issues associated with their products to determine cGMP standards and processes for product manufacture and testing.

HACCP is commonly seen in the food industry, where firms identify possible hazards and implement controls to ensure the hazards are eliminated or controlled to yield acceptable levels in the food product. In a way, HACCP is similar to the risk-based approach increasingly being used in the pharmaceutical industry, where firms identify critical quality attributes (CQAs) and assess such CQAs during validation, manufacturing processes and testing to ensure that these critical parameters yield consistent results within set specifications. These critical quality attributes need to be considered during product development because quality should be designed into the process, rather than being supported largely by testing the finished product. By properly validating processes and analytical methods, firms can demonstrate that critical quality attributes are under control and yield consistent results within a batch of product (i.e., among individual units), as well as among different batches of the same product. Because e-cigarettes are rapidly evolving from a technological standpoint, companies should be especially vigilant when making any changes to their raw materials, components, manufacturing procedures or testing processes to ensure that such changes are properly assessed, documented and incorporated as part of process validation efforts. Any nonconformances and consumer complaints should also be thoroughly investigated and documented and proper corrective or preventive actions should be implemented and documented.

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Companies should also plan to conduct product testing throughout the process, including raw material and incoming component testing, in-process quality control testing, final product analysis and stability/shelf life testing.

### Organization and Training

As many newly regulated industries have historically learned, compliance is the key to continuing a successful business. For a cGMP compliance program to be successful, the message needs to come from executive leadership and set the organization's guiding values and ethical climate. GMP compliance should be emphasized by executive leadership and management and communicated to all employees. A compliant firm will also have a quality policy, a quality plan and/or quality system procedures and instructions that are defined and documented.

Not only do employees need to adopt a cGMP mindset and prioritize compliance in their job duties, but management should ensure that employees have the resources and training they need to be able to act in accordance with cGMP principles. Companies should create an independent quality control unit that is adequately supported by management and whose mission is reinforced by the firm's quality policy, to oversee quality operations. Each employee needs to have proper training to understand the role of this quality control unit, but just as importantly, employees should appreciate and prioritize their own role in ensuring product

quality and safety. To this end, employees should be trained to detect, report and correct manufacturing and testing issues as they arise.

### Supply Chain Management

Given increased scrutiny of e-cigarettes, companies should take a more holistic view of cGMP compliance by focusing on both internal and external product quality and risk management. Companies can mitigate risk through supplier quality audits and nonconformance tracking throughout the supply chain. Companies should also maintain a centralized safety and quality tracking system that can assist in product traceability efforts. While the Deeming Rule has yet to be finalized, it is never too early to emphasize good manufacturing practices both internally and by suppliers.

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[1] Family Smoking Prevention and Tobacco Control Act; Public Law 111-31 (signed into law on June 22, 2009).

[2] The Deeming Rule would also include tobacco product components or parts that are used in the consumption of a tobacco product, like e-cigarette cartridges. It would not include tobacco product accessories, like cigar cases.

[3] U.S. Food & Drug Admin., Center for Tobacco Products, Office of Regulations; Memorandum: Summary of Write-in Campaigns to Docket the FDA-2014-N-0189 (Aug. 3, 2015).

[4] See, for e.g., The Hill.com; “the FDA Has Summer to Finalize Tobacco Deeming Regs, Senate Dem Says” (May 14, 2015).

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