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HPHC Testing: Frequently Asked Questions

To create or modify a new tobacco product, including e-juice/e-cigarette brands and vape juice ingredients, you need to comply with FDA tobacco regulations and undertake Harmful and Potentially Harmful Constituents (HPHC) testing. Before marketing the product, manufacturers must first obtain permission from the FDA, per the Federal Food, Drug, and Cosmetic Act (FD&C) section 910(a).

The FDA has extended deadlines for new tobacco products that were on the market as of August 8, 2016, several times. In a final ruling, as of May 10, 2016, two compliance deadlines for obtaining FDA approval were outlined; one for submission and FDA receipt of applications and one for obtaining premarket authorization. It is unlikely that the FDA will enforce regulations during the extended compliance period. The new compliance deadline is August 8, 2021, for newly regulated combustible tobacco products and August 8, 2022, for newly regulated noncombustible products. Recently, the U.S. District Court for the District of Maryland ruled that the submission deadline for PMTAs for ENDS products will be May 12, 2020. Furthermore, manufacturers that submit product Premarket Tobacco Applications (PMTAs) on time will be subject to an extended 12-month continued compliance period.

FDA New Tobacco Regulations: Completing HPHC Testing

Submission of the PMTA *must* include reporting of **HPHCs** in tobacco and nicotine products and tobacco smoke under section 904(a)(3) of the FD&C Act. While the final rules and deadlines to submit an HPHC report for finished tobacco products have been moved several times, HPHC testing is still a necessity. As a qualified lab partner, we can help you navigate the changing regulatory landscape and prepare for timely compliance.

Frequently Asked Questions About the Process for HPHC Nicotine Testing

- **What are HPHCs?**
  HPHCs are chemicals/chemical compounds in tobacco products, including electronic cigarettes or tobacco smoke, that cause or could cause harm to smokers or nonsmokers. Every unique product must be tested for these components, ingredients, additives, and properties.

- **How many HPHCs do I need to report on?**
  There are up to 20 key analytes for HPHC testing from the full list of 93 HPHCs that new tobacco and e-liquid products that manufacturers must report on for each unique product.

- **How long does HPHC testing take?**
  Avomeen has identified the key analytes relevant for new nicotine products and has predefined HPHC protocols for simple and low-cost testing options. You'll get regular updates along the way as we work to meet your short- and long-term goals. To see how long our custom HPHC testing of your nicotine product might take, contact us.

- **How much will it cost to test for HPHCs?**
  Avomeen creates a custom solution to meet your short- and long-term needs and challenges, ultimately helping you deliver a full PMTA regulatory submission (if that is your aim). For cost estimates for HPHC testing, contact us for a quote.

- **What if I am a very small manufacturer and cannot afford testing?**
  Avomeen recommends a risk-based approach that focuses on your most popular products. Our experts are familiar with testing protocols and requirements to expedite the process and help you contain costs.

- **What are "grandfathered" products?**
  Grandfathered products are established, substantially equivalent tobacco goods that were commercially marketed in the US between Feb. 15, 2007, and March 22, 2011. In the absence of this, manufacturers and distributors of new tobacco products, including e-juice and e-cigarette brands, must submit a premarket tobacco product application (PMTA) per FD&C Act section 910(b).

- **Can I test all the flavors I sell with one test?**
  No, but Avomeen can develop a roadmap to allow quick analysis for several flavors at once.

- **How do I obtain substantial equivalence designation?**
  Substantial equivalence means that the FDA has found your new tobacco product to be substantially equivalent to an existing product. To obtain this designation, you would have to submit a Substantial Equivalence Report.

- **The products I sell are vaping products and vape liquid ingredients and are not cigarettes. Why are they being regulated?**
  Because e-cigs, vape juice ingredients, vape delivery devices, and similar products contain nicotine derived from tobacco, they are considered to be recreational, rather than therapeutic. As such, they are subject to FDA tobacco regulation under the Tobacco Control Act.

- **I sell vaping products and do not manufacture them, although sometimes I mix flavors for my customers. Is HPHC reporting the responsibility of the people I buy my products from?**
  If you operate a vape shop that mixes or prepares liquid nicotine, vape liquid ingredients, or nicotine-containing e-liquids or you create or modify electronic cigarettes or any type of ENDS in-house, you may be considered a manufacturer. That comes with the associated legal responsibilities, including HPHC testing.

- **Most of my flavors are imported. Do I have to get them tested or is that the responsibility of the importer?**
  Importers who do not own or operate a domestic establishment for manufacturing, preparing, compounding, or processing tobacco products are not required to register their establishment or provide product listings. However, they must comply with all other applicable tobacco product manufacturer requirements. If the importer operates a domestic US establishment, compliance is required.

- **Do the FDA requirements apply to the delivery mechanism? What if I sell ENDS products, but I don't manufacture them?**
  Yes, if you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import ENDS, you must comply with the requirements for manufacturers.

- **Per the deeming FDA regulation, what do my products have to say on the label?**
  All products must have a warning label that includes, "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical."

- **Can I market my product without FDA permission?**
  If your product was marketed in the US between Feb. 15, 2007, and March 22, 2011 and you also submitted a Substantial Equivalence Report by March 22, 2011, you can continue to market your product without receiving an order from the FDA.

- **What if I don't get HPHC testing performed per the deeming regulation?**
  For importers that operate a US domestic establishment that sells, manufactures, or otherwise prepares a new tobacco product, non-compliance could result in imported tobacco products being subject to refusal of admission, under section 801 of the FD&C Act. Per previously published compliance dates, manufacturers cannot manufacture products with noncompliant packages and cannot distribute such products. This applies to small-scale manufacturers. Likewise, retailers cannot offer for sale, sell, distribute, or import products with noncompliant packages. For manufacturers and vape shops that custom mix flavors, non-compliance will put you in violation of FDA regulation, with penalties ranging from warning letters and fines, to no-sale orders and seizures, injunctions, and criminal prosecution.

Avomeen is an independent testing lab proudly serving entrepreneurs, manufacturers, distributors, lawyers, other laboratories, and companies of all sizes. We are experienced with new testing standards pertaining to the e-liquids/e-cigarettes and the FDA's upcoming Premarket Tobacco Application (PMTA) requirement.

We customize our approach for every customer we serve.

Have a specific project in mind? Request a quote or ask an experienced scientist today.

LET'S WORK TOGETHER TO ACHIEVE YOUR VISION

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