AVOMEEN

PMTA Consortium Testing Program

As the September PMTA deadline draws near, many companies are either already working or starting to work through the testing and application process. To help minimize the overall cost burden for analytical testing, we've formed a consortium program of companies looking to initiate the PMTA process.

By grouping companies to test their respective products at the same time in our FDA-registered lab, we're able to achieve economies of scale due to the overall volume as well as reduced set-up time (as opposed to testing individually).

How it Works

Request More Information

- Fill out our online form for more info - just write "PMTA Consortium" in the "message" field
- A member of Avomeen's Business Development (BD) team will provide FAQs and preliminary information

Provide Details

- After reviewing preliminary information, if you're interested in pursuing the opportunity, connect with your BD contact
- Provide your BD contact with the number of SKUs/flavors you're looking to have tested, and they'll email you a quote

Confirm Intent & Partner Up

- Confirm your intent to partner with Avomeen by providing a signed quote and/or Letter of Intent (LOI)
- Refer others to Avomeen for testing (you may be eligible for a referral bonus)

Enjoy Volume-Based Pricing

- You'll be grouped with others that sign-on within a 15-day timeframe from your signing date
- Cost savings will reflect the number of companies in the consortium; a revised quote with volume-based pricing will be provided

Start the Conversation

(Up to 2 business days)

Get a Quote

(Up to 2 business days)

Partner Up

(Within 30 days)

Join the Consortium

(Within 15 days of stating intent)

PMTA: Key Analytical Tests

HPHC Testing

PMTA submissions must include reporting of what FDA has classified as harmful or potentially harmful constituents (HPHCs). HPHC testing includes:

Carcinogenic flavoring analysis (HPHC)

Synthetic flavors or flavor enhancers can contain a wide variety of cancer-causing (carcinogenic) chemicals. Some have been banned by the FDA; others are allowed up to a certain threshold. Either way, your product range will have to undergo testing to understand the make-up of each flavor.

VG/PG ratio analysis (HPHC)

For successful premarket tobacco product applications (PMTA), you must outline the ratio of vegetable glycerin (VG) and propylene glycol (PG) found in your e-liquid or e-juice products.

Metals testing (HPHC)

These studies are performed to identify metallic impurities that may be present in your product. Approximately two dozen different metals may be present in e-liquids and e-cigarettes depending on the formulation.

Emissions testing (HPHC)

To make a judgment on safety, the FDA requires emissions testing to understand the ingredients and impurities found in your electronic nicotine delivery system (ENDS).

Other Tests

In addition to HPHCs, PMTA submissions need to include scientific data to ensure product safety, including:

Particle size in vapor testing

This is an analysis of the particle size and distribution of the vapor produced by an electronic nicotine delivery system (ENDS). It's important for understanding the dose of chemicals the consumer is really absorbing.

Nicotine dosing studies

These tests help determine the amount of nicotine expressed per puff in the e-cigarette/e-liquid combination. They're performed using real-life use conditions, following the manufacturer's instructions.

Deformulation analysis

Deformulation is the "reverse engineering" of flavor packages, agents, or additives to understand what ingredients are present in your e-liquid product, including any substances that may be restricted or banned.

Stability studies

These studies are designed to assess if an e-liquid product formulation will change over time during ambient or accelerated storage conditions.

E&L (extractables & leachables) studies

E&L studies detect and identify organic and inorganic compounds that may be inadvertently released into the product, and ensure product packaging will not leach harmful chemicals into the product.

PMTA FAQs

Q: What types of nicotine products does Avomeen have experience testing?

Avomeen has experience testing ENDS devices, e-liquids, and nicotine alternative products, including nicotine salts, pouches, chewing bags, lozenges, and gums. We can test both aerosolized and liquid vape formulations.

Q: Does it really make a difference if my lab is FDA registered?

As an FDA-registered lab, Avomeen has nearly a decade of experience working with FDA regulatory submissions, including PMTA submissions. We understand how regulatory agencies and regulatory submissions work.

Q: Why test now? The deadline has been pushed back before.

FDA is cracking down and prioritizing enforcement of PMTA regulations. If you wait until the deadline passes, you'll be considered *non-compliant* and will be facing potential penalties including product seizure and fines. The PMTA filing deadline is quickly approaching, and if you start generating data now, you'll be in better standing with FDA when the September 9, 2020 filing deadline is reached.