Electronic Cigarette Product Registration Application Requirements

Product Information:

- Product name
- Product Volume
- Nicotine content level by percentage
- Characterizing flavors (List out any characterizing flavors in product)
- Product Category (Defaults to electronic cigarette)
- Product sub-category
 - Disposable e-cigarette device
 - Electronic cigarette pod or cartridge
 - Refillable e-cigarette device
 - o E-liquid
 - o Other
- FDA PMTA Tracking #
- PMTA Submission Date
- PMTA Status
 - Authorized
 - Pending
 - Pending with court order or FDA stay
- Marketing Date

Evidence:

- For each authorized product:
 - Evidence of FDA PMTA Marketing Granted Order, such as a copy of the cover page of the marketing order or other authorization issued pursuant to 21 U.S.C. § 387j and appendices that list out all products included in the PMTA
- For each pending product:
 - Evidence of pending FDA PMTA application, such as a copy of the cover page of the premarket tobacco application with evidence of receipt of the application by the FDA and appendices that list out all products included in the PMTA,
 - o Evidence that the application was submitted on or by September 9, 2020, and
 - o Evidence that the product was marketed on or before August 9, 2016

Certification:

• Utah Certification of Electronic Cigarette Products