§ 143B-245.11. Certification process.

(a) Certification. – Beginning March 1, 2025, and annually thereafter, every manufacturer of vapor products and consumable products sold for retail sale in this State, whether directly or through a distributor, retailer, or similar intermediary or intermediaries, shall execute and deliver on a form prescribed by the Secretary, a certification to the Secretary under penalty of perjury, of the following:

(1) The manufacturer received an order granted pursuant to 21 U.S.C. § 387j(c) (marketing granted order) for the vapor product or consumable product from the FDA.

(2) The manufacturer submitted a Timely Filed Premarket Tobacco Product Application as defined in G.S. 14-313(a)(3c) for the vapor product or consumable product; and the application either remains under review by the FDA or has received a denial order that has been and remains stayed by the FDA or court order, rescinded by the FDA, or vacated by a court.

(3) The manufacturer is exempt from the requirements of subdivision (1) or (2) of this subsection because the vapor product or consumable product only reflects changes to the name, brand style, or packaging of a vapor product or consumable product.

(b) Requirements for Manufacturers; Fees. – In addition to the requirements contained in subsection (a) of this section, each manufacturer shall provide to the Secretary the following:

(1) For each vapor product and consumable product offered by the manufacturer, a copy of (i) the marketing granted order issued by the FDA pursuant to 21 U.S.C. § 387j; (ii) a copy of the acceptance letter issued by the FDA pursuant to 21 U.S.C. § 387j for a Timely Filed Premarket Tobacco Product Application; or (iii) a document issued by the FDA or by a court confirming that the premarket tobacco product application has received a denial order that is not yet in effect; and

(2) An initial fee of two thousand dollars ($2,000) to offset the costs incurred by the Department of Revenue for processing the certifications and operating the directory and an annual renewal fee of five hundred dollars ($500.00) each year on March 1 to offset the costs associated with maintaining the directory and satisfying the requirements of this section for each consumable product or vapor product to be listed in the directory.

(c) Certification Form. – The certification form shall separately list each brand name, category (e.g., e-liquid, power unit, device, e-liquid cartridge, e-liquid pod, disposable), product name, and flavor for each consumable product or vapor product that is sold in this State.

(d) Confidentiality. – The information submitted by the manufacturer pursuant to subsections (a) and (b) of this section shall be considered confidential commercial or financial information for purposes of G.S. 132-1.2. The manufacturer may redact certain confidential commercial or financial information provided under subsection (a) of this section. The Secretary shall not disclose such information except as required or authorized by law.

(e) Notification of Material Changes to the Certification. – Any manufacturer submitting a certification pursuant to subsections (a) and (b) of this section shall notify the Secretary as soon as practicable but not later than 30 days of any material change to the certification, including the issuance or denial of a marketing authorization or other order by the FDA pursuant to 21 U.S.C. § 387j, or any other order or action by the FDA or any court that affects the ability of the consumable product or vapor product to be introduced or delivered into interstate commerce for commercial distribution in the United States. (2024-31, s. 2(b).)