

**438.308 Duties and responsibilities of manufacturers of nicotine vapor products.**

- (1) A manufacturer of nicotine vapor products shall:
  - (a) Only sell authorized nicotine vapor products;
  - (b) Provide information necessary to establish its product meets the definition of an authorized nicotine vapor product as defined in KRS 438.305 directly to a wholesaler or retailer distributing or selling the manufacturer's product in accordance with paragraph (d) of this subsection;
  - (c) Comply with paragraph (b) of this subsection by providing:
    1. Proof of authorization by the FDA;
    2. A copy of the first page of the communication from the FDA reflecting an acceptance for review or the submission tracking number; or
    3. If an appeal is pending, a copy of the first page of the document filed with the applicable agency or court;which may be provided and maintained in hard copy or electronic form; and
  - (d) Provide the information from paragraph (b) of this subsection directly to a:
    1. Kentucky-licensed wholesaler that the manufacturer is utilizing to distribute its product; or
    2. Retailer if the manufacturer is not utilizing a Kentucky-licensed wholesaler to distribute its product.
- (2) If the FDA or a court of competent jurisdiction takes final action that removes an authorized nicotine vapor product from the market, the manufacturer shall provide notice of the final action to any wholesaler or retailer that has purchased the vapor product from the manufacturer within thirty (30) days of the final action being taken.
- (3) A manufacturer that fails to provide the information required in subsection (1) of this section or provides false or misleading information to retailers or wholesalers violates this section and shall be subject to a fine of:
  - (a) Twenty-five thousand dollars (\$25,000) for a first citation issued for a violation of this section;
  - (b) Fifty thousand dollars (\$50,000) for a second citation issued for a violation of this section; and
  - (c) Seventy-five thousand dollars (\$75,000) for a third or subsequent citation issued for a violation of this section.

**Effective:** March 24, 2025

**History:** Amended 2025 Ky. Acts ch. 78, sec. 9, effective March 24, 2025. -- Created 2024 Ky. Acts ch. 111, sec. 4, effective January 1, 2025.