Important Notice: Eligibility for Listing in the North Carolina Department of Revenue Vapor Products and Consumable Products Directory

The following important information is addressed in this notice:

- Unincorporated Federal Law
- Eligibility of Vapor Products and Consumable Products for listing in the Department Directory
- Placement on the Department Directory Required for Retail Sales of Vapor Products and Consumable Products

This important notice addresses which vapor products and consumable products are eligible for listing in the directory and authorized for retail sale in North Carolina.

The Department previously issued an important notice regarding Session Law 2024-31 and the establishment of a directory of vapor products and consumable products. This notice provides background regarding duties of manufacturers, penalties, and other relevant information to the directory

Unincorporated Federal Law

The Tobacco Control Act granted Food and Drug Administration ("FDA") the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products to protect the public health and reduce the use of tobacco products by minors. Pub. L. No. 111-31, 123 Stat. 1776 (2009). The Act also gave FDA authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to FDA authority. *Id.* On May 5, 2016, FDA finalized its "deeming" rule, extending FDA's regulatory authority to additional tobacco products including electronic nicotine delivery systems ("ENDS"). 81 Fed. Reg. 28, 973, 28, 976 (May 10, 2016). After the rule's effective date, new deemed tobacco products (those not commercially marketed in the United States as of February 15, 2007) were required to obtain marketing authorization under Section 910 of the Food, Drug, and Cosmetic Act ("FD&C") (21 U.S.C. 387j).

In its deeming rules, FDA provided that products that were already on the market as of August 8, 2016, could remain on the market for designated periods provided they met the Agency's deadline for submission of a request for marketing authorization ("PMTA"). The FDA gave manufacturers of ENDS products until September 9, 2020, to file applications.

Thereafter, the Consolidated Appropriations Act, 2022 (Pub. L. 117-103, Sec. 111) expanded the FDA authority to regulate tobacco products. Specifically, the law provided that FDA could regulate products containing nicotine from any source, including nicotine that was not derived from tobacco (non-tobacco nicotine ("NTN")). The law further required

manufactures to submit a PMTA for NTN products by May 14, 2022, later extended to August 8, 2022, for noncombustible tobacco products, (such as most ENDS or e cigarettes).

When the North Carolina General Assembly enacted Session Law 2024-31, the definition of Timely Filed Premarket Tobacco Product Application (N.C.G.S. § 14-313(3c))specifically cites to tobacco derived nicotine products with a PMTA deadline of September 9, 2020.

Due to the language in N.C. Gen. Stat. § 14-313(3c), for a PMTA to be considered timely filed under N.C. Gen. Stat. § 143B-245.11, a PMTA must be filed by September 9, 2020, even if the product is an NTN product.

Eligibility for Vapor Products and Consumable Products for listing in the Department Directory

A manufacturer is eligible to have a vapor product or consumable product placed on the Department's directory based on action taken by the United States Food and Drug Administration ("FDA") under any the following three circumstances:

(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. (emphasis added)
(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.

Therefore, manufacturers of vapor products and consumable products who did not file a PMTA by September 9, 2020, may still have their products be placed on the directory if: (1) FDA has issued a marketing granted order.

Placement on the Directory Required for Retail Sales of Vapor Products and Consumable Products

Only vapor products and consumable products published on the Department's directory may be sold at retail in North Carolina. Vapor products and consumable products not included on the directory may not be sold for retail sale in North Carolina, either directly or through an importer, distributor, wholesaler, retailer, or similar intermediary or intermediaries.[1]

ADVISEMENT

To the extent there is any change in the rate or amount of tax, amendment to a statute or regulation, or new case law after the date of this notice, the provisions in this notice may be superseded or voided. If a written response would require the Department to interpret the law in a manner not specifically addressed in a statute, regulation, or Departmental or IRS publication, the person requesting the written response must follow the procedure (and pay

[1] N.C. Gen. Stat. § 143B-245.13.

the required fee) for requesting a private letter ruling available on the Department's website at the following address: www.ncdor.gov/documents/nc-481-request-written-determination.